

16.2.6 Individual Efficacy Response Data

Listing 16.2.6.2.5 Primary and Secondary Efficacy Endpoints Randomization Set

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Missing; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3052141; Age (Year): 29; Sex: F; Race: MULTIPLE; (b) (6)							
(b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.6; PP Set: No; Baseline RT-PCR: Missing; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-14							
Yes/ 2020-11-24 (110)/5	Yes/ 2020-11-24 (110)/5	No	No	Yes/ 2020-11-23 (109)/5	Yes/ 2020-11-23 (109)/5	No	No
Subject ID: US3052209; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 40.5; PP Set: No; Baseline RT-PCR: Missing; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-25							
Yes/ 2020-11-22 (102)/5	Yes/ 2020-11-20 (100)/5	No	No	Yes/ 2020-11-20 (100)/5	Yes/ 2020-11-20 (100)/5	No	No
Subject ID: US3872154; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: No; Baseline RT-PCR: Missing; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-15							
Yes/ 2020-12-28 (139)/5	Yes/ 2020-12-28 (139)/5	No	No	Yes/ 2020-12-28 (139)/5	Yes/ 2020-12-28 (139)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002004; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-10-14 (80)/5	Yes/ 2020-10-14 (80)/5	No	No	Yes/ 2020-10-14 (80)/5	Yes/ 2020-10-14 (80)/5	No	No
Subject ID: US3002031; Age (Year): 25; Sex: F; Race: MULTIPLE; (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-28/							
Yes/ 2020-09-28 (63)/3	Yes/ 2020-09-28 (63)/3	No	No	Yes/ 2020-09-28 (63)/3	Yes/ 2020-09-28 (63)/3	No	No
Subject ID: US3002037; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-28/2020-08-26							
Yes/ 2020-11-03 (99)/5	Yes/ 2020-11-03 (99)/5	No	No	Yes/ 2020-11-03 (99)/5	Yes/ 2020-11-03 (99)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*		Infection			
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3002057; Age (Year): 20; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-28							
No	No	No	No	Yes/ 2020-12-24 (149)/5	Yes/ 2020-12-24 (149)/5	No	No
Subject ID: US3002076; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
Yes/ 2020-11-16 (109)/5	Yes/ 2020-11-16 (109)/5	No	No	Yes/ 2020-11-16 (109)/5	Yes/ 2020-11-16 (109)/5	No	No
Subject ID: US3002079; Age (Year): 22; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
Yes/ 2020-11-24 (117)/5	Yes/ 2020-11-24 (117)/5	No	No	Yes/ 2020-11-23 (116)/5	Yes/ 2020-11-24 (117)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002097; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2020-09-22 (50)/5	Yes/ 2020-09-22 (50)/5	No	No	Yes/ 2020-09-22 (50)/5	Yes/ 2020-09-22 (50)/5	No	No
Subject ID: US3002106; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-03							
Yes/ 2020-11-05 (93)/5	Yes/ 2020-11-05 (93)/5	No	No	Yes/ 2020-11-05 (93)/5	Yes/ 2020-11-05 (93)/5	No	No
Subject ID: US3002165; Age (Year): 37; Sex: F; Race: OTHER: HISPANIC; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2021-01-05 (145)/5	Yes/ 2021-01-05 (145)/5	No	No	Yes/ 2021-01-05 (145)/5	Yes/ 2021-01-05 (145)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002230; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	No	No	No	Yes/ 2020-09-29 (29)/4	No	No	Yes/ 2020-09-29 (29)/4
Subject ID: US3002236; Age (Year): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-30							
Yes/ 2020-11-17 (77)/5	Yes/ 2020-11-17 (77)/5	No	No	Yes/ 2020-11-17 (77)/5	Yes/ 2020-11-17 (77)/5	No	No
Subject ID: US3002260; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
Yes/ 2020-12-02 (86)/5	Yes/ 2020-12-02 (86)/5	No	No	Yes/ 2020-12-02 (86)/5	Yes/ 2020-12-02 (86)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002279; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
Yes/ 2020-10-08 (29)/3	Yes/ 2020-10-08 (29)/3	No	No	Yes/ 2020-10-08 (29)/3	Yes/ 2020-10-08 (29)/3	No	No
Subject ID: US3002284; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
No	No	No	No	Yes/ 2020-10-08 (29)/4	No	No	Yes/ 2020-10-08 (29)/4
Subject ID: US3002302; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-09							
No	Yes/ 2020-10-09 (25)/3	No	No	Yes/ 2020-10-09 (25)/3	Yes/ 2020-10-09 (25)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	
COVID-19*		COVID-19*		Death Caused by COVID-19		Asymptomatic SARS-CoV-2 Infection	

Subject ID: US3002309; Age (Year): 43; Sex: M; Race: MULTIPLE: (b) (6); Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-14

No	No	No	No	Yes/ 2020-10-14 (29)/4	No	No	Yes/ 2020-10-14 (29)/4
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Subject ID: US3002312; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 30.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-15

Yes/ 2020-12-14 (89)/5	Yes/ 2020-12-14 (89)/5	No	No	Yes/ 2020-12-14 (89)/5	Yes/ 2020-12-14 (89)/5	No	No
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Subject ID: US3002334; Age (Year): 45; Sex: F; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 33.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-28

Yes/ 2021-01-08 (102)/5	Yes/ 2021-01-08 (102)/5	No	No	Yes/ 2021-01-08 (102)/5	Yes/ 2021-01-08 (102)/5	No	No
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Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002366; Age (Year): 35; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-16/2020-11-13							
Yes/ 2020-12-14 (60)/5	Yes/ 2020-12-14 (60)/5	No	No	Yes/ 2020-12-14 (60)/5	Yes/ 2020-12-14 (60)/5	No	No
Subject ID: US3012028; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
Yes/ 2020-12-21 (146)/5	Yes/ 2020-12-21 (146)/5	No	No	Yes/ 2020-12-21 (146)/5	Yes/ 2020-12-21 (146)/5	No	No
Subject ID: US3012105; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 19.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
No	No	No	No	Yes/ 2020-09-08 (29)/4	No	No	Yes/ 2020-09-08 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3012114; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2020-12-31 (143)/5	Yes/ 2020-12-31 (143)/5	No	No	Yes/ 2020-12-31 (143)/5	Yes/ 2020-12-31 (143)/5	No	No
Subject ID: US3012154; Age (Year): 32; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-09-18 (36)/4	Yes/ 2020-09-18 (36)/4	No	No	Yes/ 2020-09-18 (36)/4	Yes/ 2020-09-18 (36)/4	No	No
Subject ID: US3012328; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-13							
Yes/ 2020-12-18 (95)/5	Yes/ 2020-12-18 (95)/5	No	No	Yes/ 2020-12-18 (95)/5	Yes/ 2020-12-18 (95)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3012329; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-13							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2021-01-13	2021-01-13	2021-01-19	2021-01-19	2021-01-13	2021-01-13		
(121)/5	(121)/5	(127)/5	(127)/5	(121)/5	(121)/5		
Subject ID: US3012334; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/2020-11-18							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2021-01-08	2021-01-08			2021-01-08	2021-01-08		
(86)/5	(86)/5			(86)/5	(86)/5		
Subject ID: US3012358; Age (Year): 25; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-20							
No	No	No	No	Yes/	No	No	Yes/
				2020-11-20			2020-11-20
				(29)/4			(29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3022026; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-09-25							
No	No	No	No	Yes/ 2020-09-25 (61)/4	No	No	Yes/ 2020-09-25 (61)/4
Subject ID: US3022111; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-09-03							
No	Yes/ 2020-11-30 (120)/5	No	No	Yes/ 2020-11-30 (120)/5	Yes/ 2020-11-30 (120)/5	No	No
Subject ID: US3022123; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (35)/4	No	No	Yes/ 2020-09-09 (35)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3022128; Age (Year): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
No	No	No	No	Yes/ 2020-09-04 (29)/4	No	No	Yes/ 2020-09-04 (29)/4
Subject ID: US3022201; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-21							
No	No	No	No	Yes/ 2020-10-16 (58)/5	No	No	Yes/ 2020-10-16 (58)/5
Subject ID: US3022211; Age (Year): 32; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-10-07							
Yes/ 2020-12-22 (125)/5	Yes/ 2020-12-22 (125)/5	No	No	Yes/ 2020-12-21 (124)/5	Yes/ 2020-12-21 (124)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3022223; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-11-20 (93)/5	Yes/ 2020-11-20 (93)/5	No	No	Yes/ 2020-11-20 (93)/5	Yes/ 2020-11-20 (93)/5	No	No
Subject ID: US3022233; Age (Year): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-24							
Yes/ 2020-10-09 (51)/5	Yes/ 2020-10-09 (51)/5	Yes/ 2020-10-21 (63)/5	Yes/ 2020-10-21 (63)/5	Yes/ 2020-10-09 (51)/5	Yes/ 2020-10-09 (51)/5	No	No
Subject ID: US3022281; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-15							
No	No	No	No	Yes/ 2021-03-01 (193)/5	No	No	Yes/ 2021-03-01 (193)/5

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3032004; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-27							
Yes/ 2020-12-22 (149)/5	Yes/ 2020-12-22 (149)/5	No	No	Yes/ 2020-12-22 (149)/5	Yes/ 2020-12-22 (149)/5	No	No
Subject ID: US3032009; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-28/2020-08-25							
Yes/ 2020-10-28 (93)/5	Yes/ 2020-10-28 (93)/5	No	No	Yes/ 2020-10-28 (93)/5	Yes/ 2020-10-28 (93)/5	No	No
Subject ID: US3032035; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
Yes/ 2020-11-16 (111)/5	Yes/ 2020-11-16 (111)/5	No	No	Yes/ 2020-11-16 (111)/5	Yes/ 2020-11-16 (111)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3032046; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-09-02							
Yes/ 2020-10-19 (82)/5	Yes/ 2020-10-19 (82)/5	No	No	Yes/ 2020-10-19 (82)/5	Yes/ 2020-10-19 (82)/5	No	No
Subject ID: US3032084; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2020-12-01 (120)/5	Yes/ 2020-12-01 (120)/5	No	No	Yes/ 2020-11-30 (119)/5	Yes/ 2020-11-30 (119)/5	No	No
Subject ID: US3032095; Age (Year): 25; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 48.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-11-13 (101)/5	Yes/ 2020-11-13 (101)/5	No	No	Yes/ 2020-11-13 (101)/5	Yes/ 2020-11-13 (101)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3032109; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-03							
Yes/ 2020-12-04 (122)/5	Yes/ 2020-12-04 (122)/5	No	No	Yes/ 2020-12-04 (122)/5	Yes/ 2020-12-04 (122)/5	No	No
Subject ID: US3032110; Age (Year): 61; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-08							
Yes/ 2020-11-19 (107)/5	Yes/ 2020-11-19 (107)/5	Yes/ 2020-11-20 (108)/5	Yes/ 2020-11-20 (108)/5	Yes/ 2020-11-19 (107)/5	Yes/ 2020-11-19 (107)/5	No	No
Subject ID: US3032113; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 42.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-04							
Yes/ 2020-09-29 (55)/5	Yes/ 2020-09-29 (55)/5	No	No	Yes/ 2020-09-29 (55)/5	Yes/ 2020-09-29 (55)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3032120; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
No	No	No	No	Yes/ 2020-10-01 (57)/5	No	No	Yes/ 2020-10-01 (57)/5
Subject ID: US3032123; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-09							
Yes/ 2020-11-17 (104)/5	Yes/ 2020-11-17 (104)/5	No	No	Yes/ 2020-11-17 (104)/5	Yes/ 2020-11-17 (104)/5	No	No
Subject ID: US3032129; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-04							
Yes/ 2020-12-03 (120)/5	Yes/ 2020-12-03 (120)/5	No	No	Yes/ 2020-12-03 (120)/5	Yes/ 2020-12-03 (120)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3032143; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-08							
Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-01 (117)/5	No	No	Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-01 (117)/5	No	No
Subject ID: US3032153; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (33)/4	No	No	Yes/ 2020-09-09 (33)/4
Subject ID: US3032171; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/							
Yes/ 2020-09-05 (27)/3	Yes/ 2020-09-08 (30)/3	No	No	Yes/ 2020-09-08 (30)/3	Yes/ 2020-09-08 (30)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3032172; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/							
Yes/ 2020-09-01 (23)/3	Yes/ 2020-09-01 (23)/3	No	No	Yes/ 2020-09-01 (23)/3	Yes/ 2020-09-01 (23)/3	No	No
Subject ID: US3032185; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2020-11-30 (112)/5	Yes/ 2020-11-30 (112)/5	No	No	Yes/ 2020-11-30 (112)/5	Yes/ 2020-11-30 (112)/5	No	No
Subject ID: US3032187; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-11 (123)/5	Yes/ 2020-12-11 (123)/5	Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-10 (122)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3032204; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-14							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No
2020-11-11	2020-11-11	2020-11-14	2020-11-14	2020-11-11	2020-11-11	2020-11-16	
(90)/5	(90)/5	(93)/5	(93)/5	(90)/5	(90)/5	(95)/5	
Subject ID: US3032213; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-18	2020-11-18			2020-11-18	2020-11-18		
(93)/5	(93)/5			(93)/5	(93)/5		
Subject ID: US3032225; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-21							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2021-01-05	2021-01-05			2021-01-04	2021-01-04		
(140)/5	(140)/5			(139)/5	(139)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3032241; Age (Year): 73; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
No	No	No	No	Yes/ 2021-01-05 (140)/5	Yes/ 2021-01-05 (140)/5	No	No
Subject ID: US3032263; Age (Year): 65; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-22							
Yes/ 2020-12-07 (110)/5	Yes/ 2020-12-07 (110)/5	No	No	Yes/ 2020-12-07 (110)/5	Yes/ 2020-12-07 (110)/5	No	No
Subject ID: US3032278; Age (Year): 74; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-23							
Yes/ 2021-01-05 (139)/5	Yes/ 2021-01-05 (139)/5	No	No	Yes/ 2021-01-05 (139)/5	Yes/ 2021-01-05 (139)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC		Based on AC	Severe	Regardless of	Secondary	Death	
Assessments	COVID-19*	Assessments	COVID-19*	Symptomatology and Severity	Definition of COVID-19*	Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3032344; Age (Year): 22; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 30.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-02							
No	No	No	No	Yes/ 2020-11-06 (65)/5	Yes/ 2020-11-06 (65)/5	No	No
Subject ID: US3032345; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 41.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-20							
No	No	No	No	Yes/ 2020-10-20 (29)/4	No	No	Yes/ 2020-10-20 (29)/4
Subject ID: US3032350; Age (Year): 58; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 34.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-09/2020-11-09							
No	No	No	No	Yes/ 2020-11-09 (32)/4	No	No	Yes/ 2020-11-09 (32)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3042011; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-28/2020-08-27							
No	No	No	No	Yes/ 2020-11-02 (98)/5	Yes/ 2020-11-03 (99)/5	No	No
Subject ID: US3042026; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-09-01							
Yes/ 2020-10-13 (77)/5	Yes/ 2020-10-13 (77)/5	No	No	Yes/ 2020-10-13 (77)/5	Yes/ 2020-10-13 (77)/5	No	No
Subject ID: US3042028; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-27							
Yes/ 2020-09-28 (62)/5	Yes/ 2020-09-28 (62)/5	No	No	Yes/ 2020-09-28 (62)/5	Yes/ 2020-09-28 (62)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042036; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-08-27							
No	No	No	No	Yes/ 2020-09-22 (55)/5	No	No	Yes/ 2020-09-22 (55)/5
Subject ID: US3042047; Age (Year): 44; Sex: M; Race: OTHER: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-09-02							
Yes/ 2021-01-11 (162)/5	Yes/ 2021-01-11 (162)/5	Yes/ 2021-01-19 (170)/5	Yes/ 2021-01-19 (170)/5	Yes/ 2021-01-11 (162)/5	Yes/ 2021-01-11 (162)/5	No	No
Subject ID: US3042051; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/							
No	No	No	No	Yes/ 2020-08-31 (29)/3	No	No	Yes/ 2020-08-31 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042062; Age (Year): 19; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-03							
No	No	No	No	Yes/ 2020-09-03 (31)/4	No	No	Yes/ 2020-09-03 (31)/4
Subject ID: US3042069; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2020-10-30 (88)/5	Yes/ 2020-10-29 (87)/5	No	No	Yes/ 2020-10-28 (86)/5	Yes/ 2020-10-28 (86)/5	No	No
Subject ID: US3042091; Age (Year): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 38.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-29							
Yes/ 2020-09-21 (47)/3	Yes/ 2020-09-21 (47)/3	No	No	Yes/ 2020-09-21 (47)/3	Yes/ 2020-09-21 (47)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042094; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-12-07 (124)/5	Yes/ 2020-12-07 (124)/5	No	No	Yes/ 2020-12-07 (124)/5	Yes/ 2020-12-07 (124)/5	No	No
Subject ID: US3042095; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-11-17 (104)/5	Yes/ 2020-11-17 (104)/5	No	No	Yes/ 2020-11-17 (104)/5	Yes/ 2020-11-17 (104)/5	No	No
Subject ID: US3042100; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-10-20 (76)/5	Yes/ 2020-10-20 (76)/5	No	No	Yes/ 2020-10-16 (72)/5	Yes/ 2020-10-16 (72)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3042113; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (34)/4	No	No	Yes/ 2020-09-09 (34)/4
Subject ID: US3042115; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-11-06 (92)/5	Yes/ 2020-11-06 (92)/5	No	No	Yes/ 2020-11-05 (91)/5	Yes/ 2020-11-05 (91)/5	No	No
Subject ID: US3042144; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-11							
Yes/ 2020-11-21 (103)/5	Yes/ 2020-11-21 (103)/5	No	No	Yes/ 2020-11-18 (100)/5	Yes/ 2020-11-18 (100)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042152; Age (Year): 61; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-16							
Yes/ 2021-01-05 (147)/5	Yes/ 2021-01-05 (147)/5	No	No	Yes/ 2021-01-05 (147)/5	Yes/ 2021-01-05 (147)/5	No	No
Subject ID: US3042153; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-11-05 (86)/5	Yes/ 2020-11-05 (86)/5	No	No	Yes/ 2020-11-05 (86)/5	Yes/ 2020-11-05 (86)/5	No	No
Subject ID: US3042164; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-16							
No	No	No	No	Yes/ 2020-10-14 (64)/5	No	No	Yes/ 2020-10-14 (64)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042170; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-15							
No	No	No	No	Yes/ 2020-09-15 (34)/4	No	No	Yes/ 2020-09-15 (34)/4
Subject ID: US3042185; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-10							
Yes/ 2020-11-30 (110)/5	Yes/ 2020-11-30 (110)/5	No	No	Yes/ 2020-11-30 (110)/5	Yes/ 2020-11-30 (110)/5	No	No
Subject ID: US3042187; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-10							
Yes/ 2020-12-03 (113)/5	Yes/ 2020-12-03 (113)/5	Yes/ 2020-12-03 (113)/5	Yes/ 2020-12-03 (113)/5	Yes/ 2020-12-03 (113)/5	Yes/ 2020-12-03 (113)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042189; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-10							
Yes/ 2020-09-16 (35)/4	Yes/ 2020-09-16 (35)/4	No	No	Yes/ 2020-09-16 (35)/4	Yes/ 2020-09-16 (35)/4	No	No
Subject ID: US3042209; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
Yes/ 2020-09-08 (26)/3	Yes/ 2020-09-08 (26)/3	No	No	Yes/ 2020-09-08 (26)/3	Yes/ 2020-09-08 (26)/3	No	No
Subject ID: US3042213; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-11-23 (99)/5	Yes/ 2020-11-23 (99)/5	No	No	Yes/ 2020-11-23 (99)/5	Yes/ 2020-11-23 (99)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042226; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-16							
Yes/ 2020-10-28 (72)/5	Yes/ 2020-10-28 (72)/5	No	No	Yes/ 2020-10-28 (72)/5	Yes/ 2020-10-28 (72)/5	No	No
Subject ID: US3042232; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
Yes/ 2020-11-03 (78)/5	Yes/ 2020-11-03 (78)/5	No	No	Yes/ 2020-11-03 (78)/5	Yes/ 2020-11-03 (78)/5	No	No
Subject ID: US3042238; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-12-04 (108)/5	Yes/ 2020-12-04 (108)/5	No	No	Yes/ 2020-12-04 (108)/5	Yes/ 2020-12-04 (108)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042241; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-12-23 (127)/5	Yes/ 2020-12-23 (127)/5	Yes/ 2021-01-06 (141)/5	Yes/ 2020-12-24 (128)/5	Yes/ 2020-12-23 (127)/5	Yes/ 2020-12-23 (127)/5	No	No
Subject ID: US3042244; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
No	No	No	No	Yes/ 2020-11-02 (76)/5	Yes/ 2020-11-02 (76)/5	No	No
Subject ID: US3042248; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2021-01-06 (141)/5	Yes/ 2021-01-06 (141)/5	No	No	Yes/ 2021-01-06 (141)/5	Yes/ 2021-01-06 (141)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042252; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-09-24 (37)/4	Yes/ 2020-09-24 (37)/4	No	No	Yes/ 2020-09-24 (37)/4	Yes/ 2020-09-24 (37)/4	No	No
Subject ID: US3042253; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-09-24 (37)/4	Yes/ 2020-09-24 (37)/4	No	No	Yes/ 2020-09-24 (37)/4	Yes/ 2020-09-24 (37)/4	No	No
Subject ID: US3042278; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-12-09 (111)/5	Yes/ 2020-12-09 (111)/5	No	No	Yes/ 2020-12-09 (111)/5	Yes/ 2020-12-09 (111)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042288; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-21							
Yes/ 2020-11-30 (102)/5	Yes/ 2020-11-30 (102)/5	Yes/ 2020-11-30 (102)/5	Yes/ 2020-11-30 (102)/5	Yes/ 2020-11-30 (102)/5	Yes/ 2020-11-30 (102)/5	No	No
Subject ID: US3042310; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-24							
No	No	No	No	Yes/ 2020-09-24 (34)/4	No	No	Yes/ 2020-09-24 (34)/4
Subject ID: US3042316; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-24							
Yes/ 2020-12-30 (131)/5	Yes/ 2020-12-30 (131)/5	No	No	Yes/ 2020-12-30 (131)/5	Yes/ 2020-12-30 (131)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3052012; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/							
No	No	No	No	Yes/ 2020-09-02 (35)/3	Yes/ 2020-09-02 (35)/3	No	No
Subject ID: US3052281; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
No	Yes/ 2021-01-28 (162)/5	No	No	Yes/ 2021-01-28 (162)/5	Yes/ 2021-01-28 (162)/5	No	No
Subject ID: US3052315; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
No	Yes/ 2020-12-09 (104)/5	No	Yes/ 2020-12-09 (104)/5	Yes/ 2020-12-09 (104)/5	No	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3062003; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
Yes/ 2021-01-11 (165)/5	Yes/ 2021-01-11 (165)/5	No	No	Yes/ 2021-01-11 (165)/5	Yes/ 2021-01-11 (165)/5	No	No
Subject ID: US3062015; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-09-15							
Yes/ 2021-01-30 (184)/5	Yes/ 2021-01-30 (184)/5	No	No	Yes/ 2021-01-30 (184)/5	Yes/ 2021-01-30 (184)/5	No	No
Subject ID: US3062045; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 53.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
No	No	No	No	Yes/ 2020-09-26 (55)/5	Yes/ 2020-09-26 (55)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3062089; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-04							
Yes/ 2020-12-11 (129)/5	Yes/ 2020-12-11 (129)/5	No	No	Yes/ 2020-12-11 (129)/5	Yes/ 2020-12-11 (129)/5	No	No
Subject ID: US3062131; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
No	No	No	No	Yes/ 2020-11-03 (90)/5	Yes/ 2020-11-03 (90)/5	No	No
Subject ID: US3062135; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-04							
Yes/ 2020-12-10 (127)/5	Yes/ 2020-12-10 (127)/5	No	Yes/ 2020-12-10 (127)/5	Yes/ 2020-12-10 (127)/5	Yes/ 2020-12-10 (127)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3062165; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-05							
Yes/ 2021-01-04 (151)/5	Yes/ 2021-01-04 (151)/5	No	No	Yes/ 2021-01-04 (151)/5	Yes/ 2021-01-04 (151)/5	No	No
Subject ID: US3062167; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-08							
Yes/ 2020-12-10 (125)/5	Yes/ 2020-12-10 (125)/5	No	No	Yes/ 2020-12-10 (125)/5	Yes/ 2020-12-10 (125)/5	No	No
Subject ID: US3062210; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2021-01-06 (149)/5	Yes/ 2021-01-06 (149)/5	No	No	Yes/ 2021-01-06 (149)/5	Yes/ 2021-01-06 (149)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3062226; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-11							
No	No	No	No	Yes/ 2020-09-11 (30)/4	No	No	Yes/ 2020-09-11 (30)/4
Subject ID: US3062232; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
No	No	No	No	Yes/ 2020-09-11 (29)/4	No	No	Yes/ 2020-09-11 (29)/4
Subject ID: US3062312; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-09							
Yes/ 2021-01-19 (130)/5	Yes/ 2021-01-19 (130)/5	No	No	Yes/ 2021-01-19 (130)/5	Yes/ 2021-01-19 (130)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3082166; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-15							
Yes/ 2021-01-10 (116)/5	Yes/ 2021-01-10 (116)/5	No	No	Yes/ 2021-01-06 (112)/5	Yes/ 2021-01-06 (112)/5	No	No
Subject ID: US3082247; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/							
Yes/ 2020-10-15 (30)/3	Yes/ 2020-10-15 (30)/3	No	No	Yes/ 2020-10-15 (30)/3	Yes/ 2020-10-15 (30)/3	No	No
Subject ID: US3092019; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 11.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-11-17 (105)/5	Yes/ 2020-11-17 (105)/5	No	No	Yes/ 2020-11-17 (105)/5	Yes/ 2020-11-17 (105)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]								
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection		Secondary Definition of COVID-19*		Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19		
Subject ID: US3092026; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02								
Yes/ 2020-11-21 (109)/5	Yes/ 2020-11-21 (109)/5	No	No	Yes/ 2020-11-21 (109)/5	Yes/ 2020-11-21 (109)/5	No	No	
Subject ID: US3092034; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-25								
Yes/ 2020-10-30 (86)/5	Yes/ 2020-10-30 (86)/5	No	No	Yes/ 2020-10-30 (86)/5	Yes/ 2020-10-30 (86)/5	No	No	
Subject ID: US3092065; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-08								
No	No	No	No	Yes/ 2020-11-25 (111)/5	Yes/ 2020-11-25 (111)/5	No	No	

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3092130; Age (Year): 26; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-16							
Yes/ 2020-12-31 (142)/5	Yes/ 2020-12-31 (142)/5	No	No	Yes/ 2020-12-31 (142)/5	Yes/ 2020-12-31 (142)/5	No	No
Subject ID: US3092134; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-23							
Yes/ 2021-01-19 (158)/5	Yes/ 2021-01-19 (158)/5	No	No	Yes/ 2021-01-19 (158)/5	Yes/ 2021-01-19 (158)/5	No	No
Subject ID: US3092135; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 44.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-12							
Yes/ 2020-12-14 (122)/5	Yes/ 2020-12-14 (122)/5	No	No	Yes/ 2020-12-14 (122)/5	Yes/ 2020-12-14 (122)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3092162; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-21							
Yes/ 2020-11-24 (98)/5	Yes/ 2020-11-24 (98)/5	No	No	Yes/ 2020-11-24 (98)/5	Yes/ 2020-11-24 (98)/5	No	No
Subject ID: US3092163; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
Yes/ 2020-12-02 (106)/5	Yes/ 2020-12-02 (106)/5	No	No	Yes/ 2020-12-02 (106)/5	Yes/ 2020-12-02 (106)/5	No	No
Subject ID: US3092246; Age (Year): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-29							
Yes/ 2020-10-03 (38)/4	Yes/ 2020-10-03 (38)/4	No	No	Yes/ 2020-10-03 (38)/4	Yes/ 2020-10-03 (38)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3092272; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-29/2020-09-24							
Yes/ 2021-01-06 (131)/5	Yes/ 2021-01-06 (131)/5	No	No	Yes/ 2021-01-06 (131)/5	Yes/ 2021-01-06 (131)/5	No	No
Subject ID: US3102081; Age (Year): 68; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
No	No	No	No	Yes/ 2020-12-10 (130)/5	Yes/ 2020-12-10 (130)/5	No	No
Subject ID: US3102271; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-21							
Yes/ 2021-01-30 (158)/5	Yes/ 2021-01-30 (158)/5	No	No	Yes/ 2021-01-30 (158)/5	Yes/ 2021-01-30 (158)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3102276; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-23							
Yes/ 2020-12-30 (126)/5	Yes/ 2020-12-30 (126)/5	No	No	Yes/ 2020-12-30 (126)/5	Yes/ 2020-12-30 (126)/5	No	No
Subject ID: US3102283; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-23							
Yes/ 2020-11-14 (80)/5	Yes/ 2020-11-17 (83)/5	Yes/ 2020-11-15 (81)/5	Yes/ 2020-11-17 (83)/5	Yes/ 2020-11-17 (83)/5	Yes/ 2020-11-17 (83)/5	No	No
Subject ID: US3102361; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-09							
Yes/ 2020-11-25 (73)/5	Yes/ 2020-11-25 (73)/5	No	No	Yes/ 2020-11-25 (73)/5	Yes/ 2020-11-25 (73)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*		Infection			
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3102381; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 43.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-14							
Yes/ 2020-12-30 (104)/5	Yes/ 2020-12-30 (104)/5	No	No	Yes/ 2020-12-30 (104)/5	Yes/ 2020-12-30 (104)/5	No	No
Subject ID: US3112049; Age (Year): 22; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 21.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
Yes/ 2020-11-05 (98)/5	Yes/ 2020-11-05 (98)/5	No	No	Yes/ 2020-11-05 (98)/5	Yes/ 2020-11-05 (98)/5	No	No
Subject ID: US3112076; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 36.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-04							
Yes/ 2020-12-27 (146)/5	Yes/ 2020-12-27 (146)/5	No	No	Yes/ 2020-12-27 (146)/5	Yes/ 2020-12-27 (146)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3112077; Age (Year): 46; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-04							
Yes/ 2020-12-23 (142)/5	Yes/ 2020-12-23 (142)/5	No	No	Yes/ 2020-12-23 (142)/5	Yes/ 2020-12-23 (142)/5	No	No
Subject ID: US3112149; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 42.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-09							
Yes/ 2021-01-05 (152)/5	Yes/ 2021-01-05 (152)/5	No	No	Yes/ 2021-01-05 (152)/5	Yes/ 2021-01-05 (152)/5	No	No
Subject ID: US3112211; Age (Year): 24; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-12-29 (140)/5	Yes/ 2020-12-30 (141)/5	No	No	Yes/ 2020-12-30 (141)/5	Yes/ 2020-12-30 (141)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3112219; Age (Year): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-12-16 (127)/5	Yes/ 2020-12-16 (127)/5	Yes/ 2020-12-17 (128)/5	Yes/ 2020-12-17 (128)/5	Yes/ 2020-12-16 (127)/5	Yes/ 2020-12-16 (127)/5	No	No
Subject ID: US3112223; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-23							
No	Yes/ 2020-09-05 (24)/3	No	No	Yes/ 2020-09-05 (24)/3	Yes/ 2020-09-05 (24)/3	No	No
Subject ID: US3112266; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
Yes/ 2020-09-13 (31)/3	Yes/ 2020-09-13 (31)/3	No	No	Yes/ 2020-09-13 (31)/3	Yes/ 2020-09-13 (31)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3112267; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
Yes/ 2020-09-13 (31)/3	Yes/ 2020-09-13 (31)/3	No	No	Yes/ 2020-09-13 (31)/3	Yes/ 2020-09-13 (31)/3	No	No
Subject ID: US3112366; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-12-30 (129)/5	Yes/ 2020-12-30 (129)/5	No	No	Yes/ 2020-12-30 (129)/5	Yes/ 2020-12-30 (129)/5	No	No
Subject ID: US3112413; Age (Year): 25; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 20.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/							
Yes/ 2021-01-15 (142)/3	Yes/ 2021-01-15 (142)/3	No	No	Yes/ 2021-01-15 (142)/3	Yes/ 2021-01-15 (142)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3132043; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 20.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-14							
Yes/ 2020-12-16 (98)/5	Yes/ 2020-12-16 (98)/5	No	No	Yes/ 2020-12-16 (98)/5	Yes/ 2020-12-16 (98)/5	No	No
Subject ID: US3132078; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 38.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-21/2020-10-21							
Yes/ 2020-12-16 (87)/5	Yes/ 2020-12-18 (89)/5	No	No	Yes/ 2020-12-16 (87)/5	Yes/ 2020-12-16 (87)/5	No	No
Subject ID: US3132084; Age (Year): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-19							
Yes/ 2021-01-14 (114)/5	Yes/ 2021-01-14 (114)/5	Yes/ 2021-01-17 (117)/5	Yes/ 2021-01-17 (117)/5	Yes/ 2021-01-14 (114)/5	Yes/ 2021-01-14 (114)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		COVID-19*		of COVID-19*		Asymptomatic SARS-CoV-2 Infection	
Subject ID: US3132107; Age (Year): 39; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-06/2020-11-04							
No	No	No	No	Yes/ 2020-12-02 (58)/5	No	No	Yes/ 2020-12-02 (58)/5
Subject ID: US3132110; Age (Year): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 35.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-05							
Yes/ 2021-01-05 (90)/5	Yes/ 2021-01-05 (90)/5	No	No	Yes/ 2021-01-05 (90)/5	Yes/ 2021-01-05 (90)/5	No	No
Subject ID: US3142013; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 38.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-09-29							
Yes/ 2020-10-30 (93)/5	Yes/ 2020-10-30 (93)/5	Yes/ 2020-11-01 (95)/5	Yes/ 2020-11-01 (95)/5	Yes/ 2020-10-30 (93)/5	Yes/ 2020-10-30 (93)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3142034; Age (Year): 74; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-27							
Yes/ 2020-12-14 (137)/5	Yes/ 2020-12-14 (137)/5	Yes/ 2020-12-14 (137)/5	Yes/ 2020-12-14 (137)/5	Yes/ 2020-12-14 (137)/5	Yes/ 2020-12-14 (137)/5	No	No
Subject ID: US3142043; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-09-01							
Yes/ 2020-12-02 (124)/5	Yes/ 2020-12-02 (124)/5	Yes/ 2020-12-02 (124)/5	Yes/ 2020-12-02 (124)/5	Yes/ 2020-12-02 (124)/5	Yes/ 2020-12-02 (124)/5	No	No
Subject ID: US3142056; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-09-01							
Yes/ 2020-12-21 (141)/5	Yes/ 2020-12-21 (141)/5	Yes/ 2020-12-21 (141)/5	Yes/ 2020-12-21 (141)/5	Yes/ 2020-12-21 (141)/5	Yes/ 2020-12-21 (141)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3142100; Age (Year): 69; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-03							
Yes/ 2020-09-21 (49)/5	Yes/ 2020-09-23 (51)/5	Yes/ 2020-10-01 (59)/5	Yes/ 2020-09-23 (51)/5	Yes/ 2020-09-23 (51)/5	Yes/ 2020-09-23 (51)/5	No	No
Subject ID: US3142107; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-08							
No	No	No	No	Yes/ 2021-01-13 (161)/5	Yes/ 2021-01-13 (161)/5	No	No
Subject ID: US3142228; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-16							
Yes/ 2021-01-05 (142)/5	Yes/ 2021-01-05 (142)/5	No	No	Yes/ 2021-01-05 (142)/5	Yes/ 2021-01-05 (142)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3142232; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-16							
Yes/ 2020-11-21 (96)/5	Yes/ 2020-11-19 (94)/5	No	No	Yes/ 2020-11-12 (87)/5	Yes/ 2020-11-19 (94)/5	No	No
Subject ID: US3142252; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 22.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-11 (79)/5	Yes/ 2020-11-11 (79)/5	Yes/ 2020-11-11 (79)/5	Yes/ 2020-11-11 (79)/5	Yes/ 2020-11-11 (79)/5	Yes/ 2020-11-11 (79)/5	No	No
Subject ID: US3142255; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 21.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-11-16 (83)/5	Yes/ 2020-11-16 (83)/5	Yes/ 2020-11-16 (83)/5	Yes/ 2020-11-16 (83)/5	Yes/ 2020-11-16 (83)/5	Yes/ 2020-11-16 (83)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3152025; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/							
Yes/ 2020-08-17 (20)/3	Yes/ 2020-08-17 (20)/3	No	No	Yes/ 2020-08-17 (20)/3	Yes/ 2020-08-17 (20)/3	No	No
Subject ID: US3152034; Age (Year): 22; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 18.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
Yes/ 2020-11-03 (98)/5	Yes/ 2020-11-03 (98)/5	No	No	Yes/ 2020-11-03 (98)/5	Yes/ 2020-11-03 (98)/5	No	No
Subject ID: US3152061; Age (Year): 24; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-09-01							
Yes/ 2020-11-03 (96)/5	Yes/ 2020-11-03 (96)/5	No	No	Yes/ 2020-11-03 (96)/5	Yes/ 2020-11-03 (96)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3152088; Age (Year): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-03							
Yes/ 2020-12-01 (119)/5	Yes/ 2020-12-01 (119)/5	No	No	Yes/ 2020-12-01 (119)/5	Yes/ 2020-12-01 (119)/5	No	No
Subject ID: US3152117; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-10							
No	No	No	No	Yes/ 2021-01-03 (150)/5	Yes/ 2021-01-03 (150)/5	No	No
Subject ID: US3152169; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-11							
Yes/ 2021-01-05 (146)/5	Yes/ 2021-01-05 (146)/5	No	No	Yes/ 2021-01-05 (146)/5	Yes/ 2021-01-05 (146)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3152189; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-15							
Yes/ 2020-11-23 (102)/5	Yes/ 2020-11-30 (109)/5	No	No	Yes/ 2020-11-23 (102)/5	Yes/ 2020-11-30 (109)/5	No	No
Subject ID: US3152211; Age (Year): 25; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-16							
Yes/ 2020-11-17 (96)/5	Yes/ 2020-11-17 (96)/5	No	No	Yes/ 2020-11-17 (96)/5	Yes/ 2020-11-17 (96)/5	No	No
Subject ID: US3152259; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-15							
No	No	No	No	Yes/ 2020-10-23 (70)/5	Yes/ 2020-10-23 (70)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3152297; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-16							
No	No	No	No	Yes/ 2020-12-29 (134)/5	No	No	No
Subject ID: US3152455; Age (Year): 42; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-12							
Yes/ 2020-12-30 (84)/5	Yes/ 2020-12-30 (84)/5	No	No	Yes/ 2020-12-30 (84)/5	Yes/ 2020-12-30 (84)/5	No	No
Subject ID: US3152486; Age (Year): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-14/2020-11-12							
Yes/ 2020-12-31 (79)/5	Yes/ 2020-12-31 (79)/5	No	No	Yes/ 2020-12-31 (79)/5	Yes/ 2020-12-31 (79)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3152499; Age (Year): 47; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/2020-11-13							
Yes/ 2020-11-20 (37)/4	Yes/ 2020-11-20 (37)/4	No	No	Yes/ 2020-11-20 (37)/4	Yes/ 2020-11-20 (37)/4	No	No
Subject ID: US3152522; Age (Year): 25; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-20							
Yes/ 2021-01-14 (86)/5	Yes/ 2021-01-14 (86)/5	No	No	Yes/ 2021-01-14 (86)/5	Yes/ 2021-01-14 (86)/5	No	No
Subject ID: US3152523; Age (Year): 71; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-18							
Yes/ 2021-01-05 (77)/5	Yes/ 2021-01-05 (77)/5	Yes/ 2021-01-07 (79)/5	Yes/ 2021-01-05 (77)/5	Yes/ 2021-01-05 (77)/5	Yes/ 2021-01-05 (77)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162006; Age (Year): 75; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-11-10 (107)/5	Yes/ 2020-11-10 (107)/5	Yes/ 2020-11-15 (112)/5	Yes/ 2020-11-10 (107)/5	Yes/ 2020-11-10 (107)/5	Yes/ 2020-11-10 (107)/5	No	No
Subject ID: US3162028; Age (Year): 67; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-08-27							
Yes/ 2020-12-28 (152)/5	Yes/ 2020-12-28 (152)/5	Yes/ 2021-01-01 (156)/5	Yes/ 2021-01-01 (156)/5	Yes/ 2020-12-28 (152)/5	Yes/ 2020-12-28 (152)/5	No	No
Subject ID: US3162034; Age (Year): 28; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 38.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
Yes/ 2020-12-26 (149)/5	Yes/ 2020-12-26 (149)/5	No	No	Yes/ 2020-12-26 (149)/5	Yes/ 2020-12-26 (149)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162044; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-12-01 (121)/5	Yes/ 2020-12-01 (121)/5	No	No	Yes/ 2020-11-25 (115)/5	Yes/ 2020-11-25 (115)/5	No	No
Subject ID: US3162047; Age (Year): 72; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-12-23 (143)/5	Yes/ 2020-12-23 (143)/5	No	No	Yes/ 2020-12-23 (143)/5	Yes/ 2020-12-23 (143)/5	No	No
Subject ID: US3162051; Age (Year): 21; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-02							
Yes/ 2020-12-15 (134)/5	Yes/ 2020-12-15 (134)/5	No	No	Yes/ 2020-12-15 (134)/5	Yes/ 2020-12-15 (134)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162124; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-18							
No	No	No	No	Yes/ 2020-09-18 (36)/4	No	No	Yes/ 2020-09-18 (36)/4
Subject ID: US3162149; Age (Year): 26; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-15							
Yes/ 2020-12-04 (108)/5	Yes/ 2020-12-04 (108)/5	No	No	Yes/ 2020-12-04 (108)/5	Yes/ 2020-12-04 (108)/5	No	No
Subject ID: US3162188; Age (Year): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-12-02 (99)/5	Yes/ 2020-12-02 (99)/5	No	No	Yes/ 2020-12-02 (99)/5	Yes/ 2020-12-02 (99)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162203; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-23							
Yes/ 2021-01-01 (127)/5	Yes/ 2021-01-01 (127)/5	No	No	Yes/ 2021-01-01 (127)/5	Yes/ 2021-01-01 (127)/5	No	No
Subject ID: US3162215; Age (Year): 28; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-30							
Yes/ 2020-12-07 (97)/5	Yes/ 2020-12-07 (97)/5	No	No	Yes/ 2020-12-07 (97)/5	Yes/ 2020-12-07 (97)/5	No	No
Subject ID: US3162219; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-01							
Yes/ 2020-12-24 (113)/5	Yes/ 2020-12-24 (113)/5	No	No	Yes/ 2020-12-24 (113)/5	Yes/ 2020-12-24 (113)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3162261; Age (Year): 41; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-05/2020-11-02							
Yes/ 2020-12-22 (79)/5	Yes/ 2020-12-22 (79)/5	No	No	Yes/ 2020-12-22 (79)/5	Yes/ 2020-12-22 (79)/5	No	No
Subject ID: US3162271; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-09/2020-11-06							
Yes/ 2020-12-01 (54)/5	Yes/ 2020-12-01 (54)/5	No	No	Yes/ 2020-12-01 (54)/5	Yes/ 2020-12-01 (54)/5	No	No
Subject ID: US3162283; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/2020-11-12							
Yes/ 2020-12-04 (51)/5	Yes/ 2020-12-04 (51)/5	No	No	Yes/ 2020-12-04 (51)/5	Yes/ 2020-12-04 (51)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162299; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-19							
Yes/ 2021-01-12 (83)/5	Yes/ 2021-01-12 (83)/5	No	No	Yes/ 2021-01-12 (83)/5	Yes/ 2021-01-12 (83)/5	No	No
Subject ID: US3162301; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 39.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-18							
Yes/ 2020-12-28 (68)/5	Yes/ 2020-12-28 (68)/5	No	No	Yes/ 2020-12-28 (68)/5	Yes/ 2020-12-28 (68)/5	No	No
Subject ID: US3172043; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2020-12-21 (133)/5	Yes/ 2020-12-21 (133)/5	No	No	Yes/ 2020-12-21 (133)/5	Yes/ 2020-12-21 (133)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3172102; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-10-22 (70)/5	Yes/ 2020-10-22 (70)/5	No	No	Yes/ 2020-10-22 (70)/5	Yes/ 2020-10-22 (70)/5	No	No
Subject ID: US3172105; Age (Year): 75; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-10-22 (70)/5	Yes/ 2020-10-22 (70)/5	No	No	Yes/ 2020-10-22 (70)/5	Yes/ 2020-10-22 (70)/5	No	No
Subject ID: US3172234; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 40.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2021-01-15 (149)/5	Yes/ 2021-01-15 (149)/5	No	Yes/ 2021-01-15 (149)/5	Yes/ 2021-01-15 (149)/5	Yes/ 2021-01-15 (149)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3172255; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 39.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/							
No	No	No	No	Yes/ 2020-10-29 (71)/3	No	No	Yes/ 2020-10-29 (71)/3
Subject ID: US3172260; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/							
No	No	No	No	Yes/ 2020-10-14 (55)/3	No	No	Yes/ 2020-10-14 (55)/3
Subject ID: US3172462; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 38.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-19							
Yes/ 2021-01-20 (92)/5	Yes/ 2021-01-20 (92)/5	No	No	Yes/ 2021-01-20 (92)/5	Yes/ 2021-01-20 (92)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3172471; Age (Year): 32; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-18							
No	No	No	No	Yes/ 2020-11-18 (29)/4	No	No	Yes/ 2020-11-18 (29)/4
Subject ID: US3182006; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-12-30 (157)/5	Yes/ 2020-12-30 (157)/5	Yes/ 2021-01-01 (159)/5	Yes/ 2021-01-01 (159)/5	Yes/ 2020-12-30 (157)/5	Yes/ 2020-12-30 (157)/5	No	No
Subject ID: US3182012; Age (Year): 32; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-21							
Yes/ 2020-11-22 (119)/5	Yes/ 2020-11-22 (119)/5	Yes/ 2020-11-22 (119)/5	Yes/ 2020-11-22 (119)/5	Yes/ 2020-11-22 (119)/5	Yes/ 2020-11-22 (119)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3182021; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-28/2020-08-28							
Yes/ 2020-10-09 (74)/5	Yes/ 2020-10-14 (79)/5	No	No	Yes/ 2020-10-14 (79)/5	Yes/ 2020-10-14 (79)/5	No	No
Subject ID: US3182050; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-09-02							
Yes/ 2020-12-28 (153)/5	Yes/ 2020-12-28 (153)/5	No	No	Yes/ 2020-12-28 (153)/5	Yes/ 2020-12-28 (153)/5	No	No
Subject ID: US3182098; Age (Year): 47; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-09-02							
No	No	No	No	Yes/ 2020-09-02 (35)/4	No	No	Yes/ 2020-09-02 (35)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3182103; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 47.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-09-01							
Yes/ 2020-12-14 (137)/5	Yes/ 2020-12-07 (130)/5	No	No	Yes/ 2020-12-07 (130)/5	Yes/ 2020-12-07 (130)/5	No	No
Subject ID: US3182145; Age (Year): 51; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2021-01-04 (154)/5	Yes/ 2021-01-04 (154)/5	Yes/ 2021-01-05 (155)/5	Yes/ 2021-01-05 (155)/5	Yes/ 2021-01-04 (154)/5	Yes/ 2021-01-04 (154)/5	No	No
Subject ID: US3182155; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-02							
No	No	No	No	Yes/ 2020-09-02 (30)/4	No	No	Yes/ 2020-09-02 (30)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3182211; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
No	No	No	No	Yes/ 2021-02-14 (193)/5	No	No	Yes/ 2021-03-01 (208)/5
Subject ID: US3182238; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-11-20 (106)/5	Yes/ 2020-11-19 (105)/5	No	No	Yes/ 2020-11-19 (105)/5	Yes/ 2020-11-19 (105)/5	No	No
Subject ID: US3182242; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 45.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-14							
Yes/ 2020-11-24 (103)/5	Yes/ 2020-11-24 (103)/5	No	No	Yes/ 2020-11-24 (103)/5	Yes/ 2020-11-24 (103)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection				
COVID-19*		COVID-19*		Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3182362; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-21							
No	No	No	No	Yes/ 2020-10-06 (51)/5	Yes/ 2020-10-06 (51)/5	No	No
Subject ID: US3192060; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): ; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-03							
No	No	No	No	Yes/ 2020-09-29 (56)/5	No	No	Yes/ 2020-09-29 (56)/5
Subject ID: US3192111; Age (Year): 18; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-11 (127)/5	Yes/ 2020-12-11 (127)/5	No	No	Yes/ 2020-12-11 (127)/5	Yes/ 2020-12-11 (127)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3192155; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-04							
Yes/ 2020-12-10 (123)/5	Yes/ 2020-12-10 (123)/5	No	No	Yes/ 2020-12-10 (123)/5	Yes/ 2020-12-10 (123)/5	No	No
Subject ID: US3192201; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-10							
Yes/ 2020-11-24 (105)/5	Yes/ 2020-11-24 (105)/5	No	No	Yes/ 2020-11-24 (105)/5	Yes/ 2020-11-24 (105)/5	No	No
Subject ID: US3192335; Age (Year): 69; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-12-16 (114)/5	Yes/ 2020-12-16 (114)/5	No	No	Yes/ 2020-12-16 (114)/5	Yes/ 2020-12-16 (114)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3192400; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2021-01-15 (148)/5	Yes/ 2021-01-15 (148)/5	No	No	Yes/ 2021-01-15 (148)/5	Yes/ 2021-01-15 (148)/5	No	No
Subject ID: US3192417; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-20							
Yes/ 2020-12-30 (131)/5	Yes/ 2020-12-30 (131)/5	No	No	Yes/ 2020-12-30 (131)/5	Yes/ 2020-12-30 (131)/5	No	No
Subject ID: US3192441; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-23/2020-09-20							
Yes/ 2021-01-04 (135)/5	Yes/ 2021-01-04 (135)/5	No	No	Yes/ 2021-01-04 (135)/5	Yes/ 2021-01-04 (135)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3192458; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-12-09 (108)/5	Yes/ 2020-12-09 (108)/5	No	No	Yes/ 2020-12-09 (108)/5	Yes/ 2020-12-09 (108)/5	No	No
Subject ID: US3192466; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-12-28 (126)/5	Yes/ 2020-12-28 (126)/5	No	No	Yes/ 2020-12-28 (126)/5	Yes/ 2020-12-28 (126)/5	No	No
Subject ID: US3192487; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-12-21 (118)/5	Yes/ 2020-12-21 (118)/5	No	No	Yes/ 2020-12-21 (118)/5	Yes/ 2020-12-21 (118)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3192501; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-30	2020-11-30			2020-11-30	2020-11-30		
(97)/5	(97)/5			(97)/5	(97)/5		
Subject ID: US3192531; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-26							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-16	2020-11-16			2020-11-16	2020-11-16		
(82)/5	(82)/5			(82)/5	(82)/5		
Subject ID: US3192563; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-12-03	2020-12-03			2020-12-03	2020-12-03		
(98)/5	(98)/5			(98)/5	(98)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3192564; Age (Year): 26; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/ 2020-12-07 (102)/5	Yes/ 2020-12-07 (102)/5	No	No	Yes/ 2020-12-07 (102)/5	Yes/ 2020-12-07 (102)/5	No	No
Subject ID: US3192569; Age (Year): 76; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-29/2020-09-26							
Yes/ 2021-01-08 (133)/5	Yes/ 2021-01-08 (133)/5	No	No	Yes/ 2021-01-08 (133)/5	Yes/ 2021-01-08 (133)/5	No	No
Subject ID: US3192622; Age (Year): 26; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-26							
Yes/ 2021-01-04 (126)/5	Yes/ 2021-01-04 (126)/5	No	No	Yes/ 2021-01-04 (126)/5	Yes/ 2021-01-04 (126)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3192732; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-04/2020-11-02							
Yes/ 2020-12-11 (69)/5	Yes/ 2020-12-11 (69)/5	No	No	Yes/ 2020-12-11 (69)/5	Yes/ 2020-12-11 (69)/5	No	No
Subject ID: US3192805; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-10							
No	No	No	No	Yes/ 2020-11-10 (29)/4	No	No	Yes/ 2020-11-10 (29)/4
Subject ID: US3192824; Age (Year): 49; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 43.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/2020-11-12							
Yes/ 2020-12-10 (57)/5	Yes/ 2020-12-10 (57)/5	No	No	Yes/ 2020-12-10 (57)/5	Yes/ 2020-12-10 (57)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3192856; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 19.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-19/2020-11-13							
Yes/ 2021-01-07 (81)/5	Yes/ 2021-01-07 (81)/5	No	No	Yes/ 2021-01-07 (81)/5	Yes/ 2021-01-07 (81)/5	No	No
Subject ID: US3202017; Age (Year): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-12-23 (141)/5	Yes/ 2020-12-23 (141)/5	No	No	Yes/ 2020-12-23 (141)/5	Yes/ 2020-12-23 (141)/5	No	No
Subject ID: US3202047; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-11							
Yes/ 2020-11-06 (92)/5	Yes/ 2020-11-06 (92)/5	No	No	Yes/ 2020-11-06 (92)/5	Yes/ 2020-11-06 (92)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3202049; Age (Year): 68; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-03							
Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-03 (119)/5	Yes/ 2020-12-03 (119)/5	Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-01 (117)/5	No	No
Subject ID: US3202125; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-24							
Yes/ 2021-01-04 (147)/5	Yes/ 2021-01-04 (147)/5	No	No	Yes/ 2021-01-04 (147)/5	Yes/ 2021-01-04 (147)/5	No	No
Subject ID: US3202152; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-09-21 (41)/4	Yes/ 2020-09-21 (41)/4	No	No	Yes/ 2020-09-21 (41)/4	Yes/ 2020-09-21 (41)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection			
COVID-19* Based on AC Assessments		COVID-19* Based on AC Assessments		Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	
COVID-19*		COVID-19*		Death Caused by COVID-19		Asymptomatic SARS-CoV-2 Infection	
Subject ID: US3202154; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-15							
Yes/2020-12-21 (132)/5	Yes/2020-12-21 (132)/5	No	No	Yes/2020-12-21 (132)/5	Yes/2020-12-21 (132)/5	No	No
Subject ID: US3202196; Age (Year): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 41.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-14							
No	No	No	No	Yes/2020-09-14 (31)/4	No	No	Yes/2020-09-14 (31)/4
Subject ID: US3202210; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-17							
Yes/2020-11-16 (94)/5	Yes/2020-11-16 (94)/5	No	No	Yes/2020-11-16 (94)/5	Yes/2020-11-16 (94)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3202253; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
Yes/ 2021-01-07 (142)/5	Yes/ 2021-01-07 (142)/5	No	No	Yes/ 2021-01-07 (142)/5	Yes/ 2021-01-07 (142)/5	No	No
Subject ID: US3202268; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 18.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-11-25 (98)/5	Yes/ 2020-11-25 (98)/5	No	No	Yes/ 2020-11-25 (98)/5	Yes/ 2020-11-25 (98)/5	No	No
Subject ID: US3202314; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-12-28 (126)/5	Yes/ 2020-12-28 (126)/5	No	No	Yes/ 2020-12-28 (126)/5	Yes/ 2020-12-28 (126)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3202328; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-21							
Yes/ 2020-12-01 (98)/5	Yes/ 2020-12-01 (98)/5	No	No	Yes/ 2020-12-01 (98)/5	Yes/ 2020-12-01 (98)/5	No	No
Subject ID: US3202346; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-10-09 (44)/5	Yes/ 2020-10-09 (44)/5	No	No	Yes/ 2020-10-09 (44)/5	Yes/ 2020-10-09 (44)/5	No	No
Subject ID: US3202350; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-10-06							
Yes/ 2020-12-11 (107)/5	Yes/ 2020-12-11 (107)/5	No	No	Yes/ 2020-12-11 (107)/5	Yes/ 2020-12-11 (107)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3202405; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2020-11-30 (83)/5	Yes/ 2020-11-30 (83)/5	No	No	Yes/ 2020-11-30 (83)/5	Yes/ 2020-11-30 (83)/5	No	No
Subject ID: US3212004; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-12-05 (125)/5	Yes/ 2020-12-04 (124)/5	No	No	Yes/ 2020-12-04 (124)/5	Yes/ 2020-12-04 (124)/5	No	No
Subject ID: US3212027; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2020-12-17 (136)/5	Yes/ 2020-12-17 (136)/5	No	No	Yes/ 2020-12-17 (136)/5	Yes/ 2020-12-17 (136)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3212038; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
No	No	No	No	Yes/ 2020-09-01 (29)/4	No	No	Yes/ 2020-09-01 (29)/4
Subject ID: US3212044; Age (Year): 31; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-09-30 (57)/5	Yes/ 2020-09-30 (57)/5	No	No	Yes/ 2020-09-30 (57)/5	Yes/ 2020-09-30 (57)/5	No	No
Subject ID: US3212112; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/							
Yes/ 2020-10-29 (81)/3	Yes/ 2020-10-29 (81)/3	Yes/ 2020-11-09 (92)/3	Yes/ 2020-11-09 (92)/3	Yes/ 2020-10-29 (81)/3	Yes/ 2020-10-29 (81)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3212115; Age (Year): 82; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-10 (122)/5	No	No	Yes/ 2020-12-08 (120)/5	Yes/ 2020-12-08 (120)/5	No	No
Subject ID: US3212133; Age (Year): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT REPORTED; BMI (kg/m ²): 34.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-11							
Yes/ 2020-12-12 (124)/5	Yes/ 2020-12-11 (123)/5	No	No	Yes/ 2020-12-11 (123)/5	Yes/ 2020-12-11 (123)/5	No	No
Subject ID: US3212140; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-12-10 (121)/5	Yes/ 2020-12-10 (121)/5	No	No	Yes/ 2020-12-10 (121)/5	Yes/ 2020-12-10 (121)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3212149; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-12-04 (115)/5	Yes/ 2020-12-04 (115)/5	No	No	Yes/ 2020-12-04 (115)/5	Yes/ 2020-12-04 (115)/5	No	No
Subject ID: US3212150; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-15							
Yes/ 2021-01-27 (169)/5	Yes/ 2021-01-27 (169)/5	No	No	Yes/ 2021-01-27 (169)/5	Yes/ 2021-01-27 (169)/5	No	No
Subject ID: US3212151; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-11-09 (90)/5	Yes/ 2020-11-09 (90)/5	No	No	Yes/ 2020-11-09 (90)/5	Yes/ 2020-11-09 (90)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3212180; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-29 (138)/5	Yes/ 2020-12-29 (138)/5	No	No	Yes/ 2020-12-29 (138)/5	Yes/ 2020-12-29 (138)/5	No	No
Subject ID: US3212241; Age (Year): 41; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-21							
No	No	No	No	Yes/ 2021-01-11 (146)/5	Yes/ 2021-01-11 (146)/5	No	No
Subject ID: US3212261; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-23							
Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-04 (138)/5	No	No	Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-04 (138)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3212304; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
No	No	No	No	Yes/ 2020-11-18 (86)/5	Yes/ 2020-11-18 (86)/5	No	No
Subject ID: US3212311; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-21							
No	No	No	No	Yes/ 2021-01-13 (141)/5	Yes/ 2021-01-13 (141)/5	No	No
Subject ID: US3212396; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-15							
Yes/ 2021-01-08 (120)/5	Yes/ 2021-01-08 (120)/5	No	No	Yes/ 2021-01-08 (120)/5	Yes/ 2021-01-08 (120)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3222216; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-10-10							
Yes/ 2020-09-14 (27)/3	Yes/ 2020-11-16 (90)/5	No	No	Yes/ 2020-11-16 (90)/5	Yes/ 2020-11-16 (90)/5	No	No
Subject ID: US3222285; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-19							
Yes/ 2020-12-22 (123)/5	Yes/ 2020-12-22 (123)/5	No	No	Yes/ 2020-12-22 (123)/5	Yes/ 2020-12-22 (123)/5	No	No
Subject ID: US3222424; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/							
Yes/ 2020-09-10 (11)/2	Yes/ 2020-09-10 (11)/2	No	No	Yes/ 2020-09-10 (11)/2	Yes/ 2020-09-10 (11)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3222430; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-10-01							
Yes/ 2021-01-07 (129)/5	Yes/ 2021-01-07 (129)/5	No	No	Yes/ 2021-01-06 (128)/5	Yes/ 2021-01-06 (128)/5	No	No
Subject ID: US3222450; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-10-01							
Yes/ 2020-12-12 (102)/5	Yes/ 2020-12-12 (102)/5	No	No	Yes/ 2020-12-12 (102)/5	Yes/ 2020-12-12 (102)/5	No	No
Subject ID: US3222487; Age (Year): 65; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-01							
Yes/ 2021-01-13 (132)/5	Yes/ 2021-01-12 (131)/5	No	No	Yes/ 2021-01-12 (131)/5	Yes/ 2021-01-12 (131)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3222657; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-01/2020-10-30							
Yes/ 2020-12-28 (89)/5	Yes/ 2020-12-28 (89)/5	No	No	Yes/ 2020-12-27 (88)/5	Yes/ 2020-12-28 (89)/5	No	No
Subject ID: US3232028; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-11-23 (104)/5	Yes/ 2020-11-23 (104)/5	No	No	Yes/ 2020-11-23 (104)/5	Yes/ 2020-11-23 (104)/5	No	No
Subject ID: US3232056; Age (Year): 72; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2021-01-08 (145)/5	Yes/ 2021-01-08 (145)/5	Yes/ 2021-01-27 (164)/5	Yes/ 2021-01-27 (164)/5	Yes/ 2021-01-08 (145)/5	Yes/ 2021-01-08 (145)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3232103; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-10-19 (56)/5	Yes/ 2020-10-19 (56)/5	No	No	Yes/ 2020-10-19 (56)/5	Yes/ 2020-10-19 (56)/5	No	No
Subject ID: US3232137; Age (Year): 21; Sex: F; Race: OTHER: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2021-01-15 (137)/5	Yes/ 2021-01-15 (137)/5	No	No	Yes/ 2021-01-15 (137)/5	Yes/ 2021-01-15 (137)/5	No	No
Subject ID: US3232145; Age (Year): 20; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-01							
Yes/ 2020-10-05 (33)/4	Yes/ 2020-10-05 (33)/4	No	No	Yes/ 2020-10-05 (33)/4	Yes/ 2020-10-05 (33)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3232157; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2021-01-08 (122)/5	Yes/ 2021-01-08 (122)/5	Yes/ 2021-01-10 (124)/5	Yes/ 2021-01-10 (124)/5	Yes/ 2021-01-08 (122)/5	Yes/ 2021-01-08 (122)/5	No	No
Subject ID: US3242002; Age (Year): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 42.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/							
Yes/ 2020-08-12 (7)/2	Yes/ 2020-08-12 (7)/2	No	No	Yes/ 2020-08-12 (7)/2	Yes/ 2020-08-12 (7)/2	No	No
Subject ID: US3242003; Age (Year): 67; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 49.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-04							
Yes/ 2021-01-23 (171)/5	Yes/ 2021-01-23 (171)/5	Yes/ 2021-01-28 (176)/5	Yes/ 2021-01-28 (176)/5	Yes/ 2021-01-23 (171)/5	Yes/ 2021-01-23 (171)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3242026; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (34)/4	No	No	Yes/ 2020-09-09 (34)/4
Subject ID: US3242047; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-10							
Yes/ 2020-12-28 (143)/5	Yes/ 2020-12-28 (143)/5	No	No	Yes/ 2020-12-28 (143)/5	Yes/ 2020-12-28 (143)/5	No	No
Subject ID: US3242089; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-11-04 (83)/5	Yes/ 2020-11-04 (83)/5	No	No	Yes/ 2020-11-04 (83)/5	Yes/ 2020-11-04 (83)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3242112; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-15							
Yes/ 2020-10-29 (74)/5	Yes/ 2020-10-29 (74)/5	No	No	Yes/ 2020-10-29 (74)/5	Yes/ 2020-10-29 (74)/5	No	No
Subject ID: US3242127; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-16							
Yes/ 2020-11-30 (105)/5	Yes/ 2020-11-30 (105)/5	No	No	Yes/ 2020-11-30 (105)/5	Yes/ 2020-11-30 (105)/5	No	No
Subject ID: US3242140; Age (Year): 68; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-18							
No	No	No	No	Yes/ 2020-10-20 (63)/5	No	No	Yes/ 2020-10-20 (63)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3242153; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
Yes/ 2020-12-08 (112)/5	Yes/ 2020-12-08 (112)/5	No	No	Yes/ 2020-12-08 (112)/5	Yes/ 2020-12-08 (112)/5	No	No
Subject ID: US3242226; Age (Year): 31; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-24							
Yes/ 2020-12-10 (107)/5	Yes/ 2020-12-10 (107)/5	No	No	Yes/ 2020-12-10 (107)/5	Yes/ 2020-12-10 (107)/5	No	No
Subject ID: US3242230; Age (Year): 75; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-25							
Yes/ 2020-11-10 (76)/5	Yes/ 2020-11-10 (76)/5	No	No	Yes/ 2020-11-10 (76)/5	Yes/ 2020-11-10 (76)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic SARS-CoV-2 Infection	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	
Subject ID: US3242276; Age (Year): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-10-01							
Yes/2021-01-28 (149)/5	Yes/2021-01-28 (149)/5	No	No	Yes/2021-01-28 (149)/5	Yes/2021-01-28 (149)/5	No	No
Subject ID: US3242384; Age (Year): 48; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-25/2020-10-26							
Yes/2020-12-09 (76)/5	Yes/2020-12-09 (76)/5	No	No	Yes/2020-12-09 (76)/5	Yes/2020-12-09 (76)/5	No	No
Subject ID: US3242385; Age (Year): 46; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-25/2020-10-26							
No	No	No	No	Yes/2020-11-24 (61)/5	No	No	Yes/2020-11-24 (61)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3242397; Age (Year): 48; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-27							
Yes/ 2020-11-05 (38)/4	Yes/ 2020-11-01 (34)/4	Yes/ 2020-11-08 (41)/4	Yes/ 2020-11-06 (39)/4	Yes/ 2020-11-01 (34)/4	Yes/ 2020-11-01 (34)/4	No	No
Subject ID: US3242398; Age (Year): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 44.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-29							
Yes/ 2021-01-19 (113)/5	Yes/ 2021-01-19 (113)/5	No	No	Yes/ 2021-01-19 (113)/5	Yes/ 2021-01-19 (113)/5	No	No
Subject ID: US3252020; Age (Year): 24; Sex: M; Race: NOT REPORTED; Ethnicity: NOT REPORTED; BMI (kg/m²): 27.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/							
Yes/ 2020-08-17 (14)/2	Yes/ 2020-08-17 (14)/2	No	No	Yes/ 2020-08-17 (14)/2	Yes/ 2020-08-17 (14)/2	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3252083; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-04							
Yes/ 2020-10-20 (74)/5	Yes/ 2020-10-20 (74)/5	No	No	Yes/ 2020-10-20 (74)/5	Yes/ 2020-10-20 (74)/5	No	No
Subject ID: US3252202; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-18							
Yes/ 2021-01-20 (159)/5	Yes/ 2021-01-20 (159)/5	No	No	Yes/ 2021-01-20 (159)/5	Yes/ 2021-01-20 (159)/5	No	No
Subject ID: US3252211; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-10-02 (47)/5	Yes/ 2020-10-02 (47)/5	No	No	Yes/ 2020-10-02 (47)/5	Yes/ 2020-10-02 (47)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3252212; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 47.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-16							
Yes/ 2020-09-30 (45)/5	Yes/ 2020-09-30 (45)/5	No	No	Yes/ 2020-09-30 (45)/5	Yes/ 2020-09-30 (45)/5	No	No
Subject ID: US3252304; Age (Year): 36; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-19							
Yes/ 2021-01-08 (140)/5	Yes/ 2021-01-08 (140)/5	No	No	Yes/ 2021-01-08 (140)/5	Yes/ 2021-01-08 (140)/5	No	No
Subject ID: US3252334; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-23							
Yes/ 2020-11-25 (93)/5	Yes/ 2020-11-25 (93)/5	No	No	Yes/ 2020-11-25 (93)/5	Yes/ 2020-11-25 (93)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3252388; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-29/2020-09-29							
Yes/ 2021-01-12 (137)/5	Yes/ 2021-01-12 (137)/5	No	No	Yes/ 2021-01-12 (137)/5	Yes/ 2021-01-12 (137)/5	No	No
Subject ID: US3252455; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-09							
Yes/ 2021-01-21 (134)/5	Yes/ 2021-01-21 (134)/5	No	No	Yes/ 2021-01-21 (134)/5	Yes/ 2021-01-21 (134)/5	No	No
Subject ID: US3252583; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 32.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/							
No	No	No	No	Yes/ 2020-10-28 (29)/3	No	No	Yes/ 2020-10-28 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3252638; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 40.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/							
Yes/ 2020-10-28 (22)/3	Yes/ 2020-10-28 (22)/3	No	No	Yes/ 2020-10-28 (22)/3	Yes/ 2020-10-28 (22)/3	No	No
Subject ID: US3252642; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-05							
Yes/ 2020-12-30 (85)/5	Yes/ 2020-12-30 (85)/5	No	No	Yes/ 2020-12-29 (84)/5	Yes/ 2020-12-29 (84)/5	No	No
Subject ID: US3252659; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-10							
Yes/ 2020-11-24 (43)/5	Yes/ 2020-11-24 (43)/5	No	No	Yes/ 2020-11-24 (43)/5	Yes/ 2020-11-24 (43)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3252700; Age (Year): 26; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-20							
Yes/ 2021-01-05 (75)/5	Yes/ 2021-01-05 (75)/5	No	No	Yes/ 2021-01-05 (75)/5	Yes/ 2021-01-05 (75)/5	No	No
Subject ID: US3262007; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-25							
Yes/ 2020-11-30 (127)/5	Yes/ 2020-11-30 (127)/5	Yes/ 2020-12-03 (130)/5	Yes/ 2020-12-03 (130)/5	Yes/ 2020-11-30 (127)/5	Yes/ 2020-11-30 (127)/5	No	No
Subject ID: US3262054; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-09-01							
Yes/ 2021-01-25 (180)/5	Yes/ 2021-01-25 (180)/5	No	No	Yes/ 2021-01-25 (180)/5	Yes/ 2021-01-25 (180)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3262099; Age (Year): 61; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-03							
Yes/ 2020-10-12 (69)/5	Yes/ 2020-10-12 (69)/5	Yes/ 2020-10-16 (73)/5	Yes/ 2020-10-16 (73)/5	Yes/ 2020-10-12 (69)/5	Yes/ 2020-10-12 (69)/5	No	No
Subject ID: US3262145; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-05							
Yes/ 2020-12-14 (129)/5	Yes/ 2020-12-14 (129)/5	Yes/ 2020-12-15 (130)/5	Yes/ 2020-12-15 (130)/5	Yes/ 2020-12-14 (129)/5	Yes/ 2020-12-14 (129)/5	No	No
Subject ID: US3262197; Age (Year): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-15							
No	No	No	No	Yes/ 2020-09-15 (30)/4	No	No	Yes/ 2020-09-15 (30)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3262275; Age (Year): 24; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-09/2020-11-10							
Yes/ 2021-01-28 (112)/5	Yes/ 2021-01-28 (112)/5	Yes/ 2021-01-31 (115)/5	Yes/ 2021-01-31 (115)/5	Yes/ 2021-01-28 (112)/5	Yes/ 2021-01-28 (112)/5	No	No
Subject ID: US3272002; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 22.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
No	No	No	No	Yes/ 2020-09-30 (64)/5	No	No	Yes/ 2020-09-30 (64)/5
Subject ID: US3272005; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 29.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/							
Yes/ 2020-12-10 (135)/3	Yes/ 2020-12-10 (135)/3	No	No	Yes/ 2020-12-10 (135)/3	Yes/ 2020-12-10 (135)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3272006; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
No	No	No	No	Yes/ 2020-08-26 (29) /4	No	No	Yes/ 2020-08-26 (29) /4
Subject ID: US3272010; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-28							
Yes/ 2020-11-20 (115) /5	Yes/ 2020-11-20 (115) /5	No	No	Yes/ 2020-11-20 (115) /5	Yes/ 2020-11-20 (115) /5	No	No
Subject ID: US3272021; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-09-01							
Yes/ 2020-12-29 (153) /5	Yes/ 2020-12-29 (153) /5	No	No	Yes/ 2020-12-29 (153) /5	Yes/ 2020-12-29 (153) /5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3272026; Age (Year): 46; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-09-08							
Yes/ 2020-11-12 (104)/5	Yes/ 2020-11-12 (104)/5	Yes/ 2020-11-16 (108)/5	Yes/ 2020-11-16 (108)/5	Yes/ 2020-11-12 (104)/5	Yes/ 2020-11-12 (104)/5	No	No
Subject ID: US3272055; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-03							
Yes/ 2020-10-05 (62)/5	Yes/ 2020-10-06 (63)/5	No	No	Yes/ 2020-10-06 (63)/5	Yes/ 2020-10-06 (63)/5	No	No
Subject ID: US3272097; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-09							
Yes/ 2020-11-20 (103)/5	Yes/ 2020-11-20 (103)/5	No	No	Yes/ 2020-11-20 (103)/5	Yes/ 2020-11-20 (103)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3272104; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2021-01-04 (147)/5	Yes/ 2021-01-04 (147)/5	Yes/ 2021-01-09 (152)/5	Yes/ 2021-01-09 (152)/5	Yes/ 2021-01-04 (147)/5	Yes/ 2021-01-04 (147)/5	No	No
Subject ID: US3272142; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-15							
Yes/ 2020-10-30 (78)/5	Yes/ 2020-10-30 (78)/5	No	No	Yes/ 2020-10-30 (78)/5	Yes/ 2020-10-30 (78)/5	No	No
Subject ID: US3272144; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-11-04 (83)/5	Yes/ 2020-11-04 (83)/5	Yes/ 2020-11-11 (90)/5	Yes/ 2020-11-11 (90)/5	Yes/ 2020-11-04 (83)/5	Yes/ 2020-11-04 (83)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3272174; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-11-06 (82)/5	Yes/ 2020-11-06 (82)/5	No	No	Yes/ 2020-11-06 (82)/5	Yes/ 2020-11-06 (82)/5	No	No
Subject ID: US3272184; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-10-30 (73)/5	Yes/ 2020-10-30 (73)/5	No	No	Yes/ 2020-10-30 (73)/5	Yes/ 2020-10-30 (73)/5	No	No
Subject ID: US3272186; Age (Year): 24; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
Yes/ 2020-11-03 (77)/5	Yes/ 2020-11-03 (77)/5	No	No	Yes/ 2020-11-03 (77)/5	Yes/ 2020-11-03 (77)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3272188; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-12-16 (120)/5	Yes/ 2020-12-16 (120)/5	No	No	Yes/ 2020-12-16 (120)/5	Yes/ 2020-12-16 (120)/5	No	No
Subject ID: US3272195; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
Yes/ 2020-11-02 (76)/5	Yes/ 2020-11-02 (76)/5	Yes/ 2020-11-03 (77)/5	Yes/ 2020-11-05 (79)/5	Yes/ 2020-11-02 (76)/5	Yes/ 2020-11-02 (76)/5	No	No
Subject ID: US3272196; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-11-09 (83)/5	Yes/ 2020-11-09 (83)/5	Yes/ 2020-11-10 (84)/5	Yes/ 2020-11-10 (84)/5	Yes/ 2020-11-09 (83)/5	Yes/ 2020-11-09 (83)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3272210; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-21							
No	Yes/ 2020-09-30 (42)/4	No	No	Yes/ 2020-09-28 (40)/4	Yes/ 2020-09-30 (42)/4	No	No
Subject ID: US3272219; Age (Year): 24; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-10-20 (62)/5	Yes/ 2020-10-20 (62)/5	No	No	Yes/ 2020-10-20 (62)/5	Yes/ 2020-10-20 (62)/5	No	No
Subject ID: US3272230; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
No	No	No	No	Yes/ 2020-09-18 (29)/4	No	No	Yes/ 2020-09-18 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3272247; Age (Year): 68; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
No	No	No	No	Yes/ 2020-09-18 (29)/4	No	No	Yes/ 2020-09-18 (29)/4
Subject ID: US3272271; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-22							
Yes/ 2020-10-28 (68)/5	Yes/ 2020-10-28 (68)/5	No	No	Yes/ 2020-10-28 (68)/5	Yes/ 2020-10-28 (68)/5	No	No
Subject ID: US3272272; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-23							
Yes/ 2021-01-15 (147)/5	Yes/ 2021-01-15 (147)/5	No	No	Yes/ 2021-01-15 (147)/5	Yes/ 2021-01-15 (147)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3272305; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-23/2020-09-22							
Yes/ 2020-10-21 (60)/5	Yes/ 2020-10-21 (60)/5	No	No	Yes/ 2020-10-21 (60)/5	Yes/ 2020-10-21 (60)/5	No	No
Subject ID: US3272317; Age (Year): 81; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-23/2020-09-24							
Yes/ 2020-11-13 (83)/5	Yes/ 2020-11-13 (83)/5	No	No	Yes/ 2020-11-13 (83)/5	Yes/ 2020-11-13 (83)/5	No	No
Subject ID: US3272329; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-23/2020-09-25							
Yes/ 2020-11-02 (72)/5	Yes/ 2020-11-02 (72)/5	No	No	Yes/ 2020-11-02 (72)/5	Yes/ 2020-11-02 (72)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*		Infection			
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3272342; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-23/2020-09-24							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2020-12-02	2020-12-02	2020-12-06	2020-12-06	2020-12-02	2020-12-02		
(102)/5	(102)/5	(106)/5	(106)/5	(102)/5	(102)/5		
Subject ID: US3272357; Age (Year): 41; Sex: F; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2020-11-10	2020-11-10	2020-11-17	2020-11-10	2020-11-10	2020-11-10		
(78)/5	(78)/5	(85)/5	(78)/5	(78)/5	(78)/5		
Subject ID: US3272361; Age (Year): 24; Sex: F; Race: OTHER: (b) (6); Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
No	Yes/	No	Yes/	Yes/	Yes/	No	No
	2020-10-06		2020-10-07	2020-10-06	2020-10-06		
	(42)/4		(43)/5	(42)/4	(42)/4		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3292109; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2021-01-07 (150)/5	Yes/ 2021-01-07 (150)/5	No	No	Yes/ 2021-01-07 (150)/5	Yes/ 2021-01-07 (150)/5	No	No
Subject ID: US3292188; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-12							
Yes/ 2021-01-20 (159)/5	Yes/ 2021-01-20 (159)/5	No	No	Yes/ 2021-01-20 (159)/5	Yes/ 2021-01-20 (159)/5	No	No
Subject ID: US3292218; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
Yes/ 2021-01-12 (148)/5	Yes/ 2021-01-12 (148)/5	No	No	Yes/ 2021-01-12 (148)/5	Yes/ 2021-01-12 (148)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3292280; Age (Year): 24; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-12-08 (110)/5	Yes/ 2020-12-08 (110)/5	No	No	Yes/ 2020-12-08 (110)/5	Yes/ 2020-12-08 (110)/5	No	No
Subject ID: US3292289; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-05 (73)/5	No	No	Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-05 (73)/5	No	No
Subject ID: US3292320; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-18 (86)/5	Yes/ 2020-11-18 (86)/5	No	No	Yes/ 2020-11-18 (86)/5	Yes/ 2020-11-18 (86)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3292395; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 38.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-15							
Yes/ 2020-11-12 (57)/5	Yes/ 2020-11-12 (57)/5	No	No	Yes/ 2020-11-11 (56)/5	Yes/ 2020-11-11 (56)/5	No	No
Subject ID: US3292407; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-20							
No	No	No	No	Yes/ 2020-10-20 (29)/4	Yes/ 2020-10-27 (36)/4	No	Yes/ 2020-10-20 (29)/4
Subject ID: US3292411; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-22							
Yes/ 2020-12-29 (97)/5	Yes/ 2020-12-29 (97)/5	No	No	Yes/ 2020-12-29 (97)/5	Yes/ 2020-12-29 (97)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3302008; Age (Year): 18; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
No	No	No	No	Yes/ 2020-08-31 (29)/4	No	No	Yes/ 2020-08-31 (29)/4
Subject ID: US3302042; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-04							
Yes/ 2020-12-22 (140)/5	Yes/ 2020-12-22 (140)/5	No	No	Yes/ 2020-12-21 (139)/5	Yes/ 2020-12-22 (140)/5	No	No
Subject ID: US3302051; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
No	No	No	No	Yes/ 2021-01-26 (175)/5	Yes/ 2021-01-26 (175)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3302062; Age (Year): 36; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-12-10 (127)/5	Yes/ 2020-12-09 (126)/5	No	No	Yes/ 2020-12-09 (126)/5	Yes/ 2020-12-09 (126)/5	No	No
Subject ID: US3302065; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-02							
No	No	No	No	Yes/ 2020-12-10 (127)/5	Yes/ 2020-12-11 (128)/5	No	No
Subject ID: US3302143; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-12-24 (136)/5	Yes/ 2020-12-24 (136)/5	No	No	Yes/ 2020-12-24 (136)/5	Yes/ 2020-12-24 (136)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3302161; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-12-14 (125)/5	Yes/ 2020-12-14 (125)/5	No	No	Yes/ 2020-12-14 (125)/5	Yes/ 2020-12-14 (125)/5	No	No
Subject ID: US3302187; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-10							
Yes/ 2020-12-28 (138)/5	Yes/ 2020-12-28 (138)/5	No	No	Yes/ 2020-12-28 (138)/5	Yes/ 2020-12-28 (138)/5	No	No
Subject ID: US3302221; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-03 (112)/5	Yes/ 2020-12-03 (112)/5	No	No	Yes/ 2020-12-03 (112)/5	Yes/ 2020-12-03 (112)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3302229; Age (Year): 28; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-12-23 (129)/5	Yes/ 2020-12-23 (129)/5	No	No	Yes/ 2020-12-23 (129)/5	Yes/ 2020-12-23 (129)/5	No	No
Subject ID: US3302236; Age (Year): 31; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-12-22 (128)/5	Yes/ 2020-12-22 (128)/5	No	No	Yes/ 2020-12-22 (128)/5	Yes/ 2020-12-22 (128)/5	No	No
Subject ID: US3302303; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
No	No	No	No	Yes/ 2021-01-14 (148)/5	Yes/ 2021-01-14 (148)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3302310; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 18.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-16							
No	Yes/ 2020-10-26 (68)/5	No	No	Yes/ 2020-10-26 (68)/5	Yes/ 2020-10-26 (68)/5	No	No
Subject ID: US3302318; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-17							
Yes/ 2020-12-29 (131)/5	Yes/ 2020-12-29 (131)/5	No	No	Yes/ 2020-12-29 (131)/5	Yes/ 2020-12-29 (131)/5	No	No
Subject ID: US3302333; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-10-12 (50)/5	Yes/ 2020-10-12 (50)/5	No	No	Yes/ 2020-10-12 (50)/5	Yes/ 2020-10-12 (50)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3302348; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-12-22 (121)/5	Yes/ 2020-12-22 (121)/5	No	No	Yes/ 2020-12-22 (121)/5	Yes/ 2020-12-22 (121)/5	No	No
Subject ID: US3302379; Age (Year): 42; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2021-01-23 (151)/5	Yes/ 2021-01-23 (151)/5	Yes/ 2021-01-23 (151)/5	Yes/ 2021-01-23 (151)/5	Yes/ 2021-01-23 (151)/5	Yes/ 2021-01-23 (151)/5	No	No
Subject ID: US3302381; Age (Year): 32; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-12-14 (111)/5	Yes/ 2020-12-14 (111)/5	No	No	Yes/ 2020-12-14 (111)/5	Yes/ 2020-12-14 (111)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3302383; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/							
Yes/ 2020-09-22 (28)/3	No	Yes/ 2020-09-28 (34)/3	No	Yes/ 2020-09-22 (28)/3	Yes/ 2020-09-22 (28)/3	No	No
Subject ID: US3302458; Age (Year): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 16.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-19							
Yes/ 2021-01-06 (107)/5	Yes/ 2021-01-06 (107)/5	No	No	Yes/ 2021-01-06 (107)/5	Yes/ 2021-01-06 (107)/5	No	No
Subject ID: US3302470; Age (Year): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-06/2020-11-03							
Yes/ 2021-01-08 (95)/5	Yes/ 2021-01-08 (95)/5	No	No	Yes/ 2021-01-08 (95)/5	Yes/ 2021-01-08 (95)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3312005; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-07							
Yes/ 2021-01-04 (148)/5	Yes/ 2021-01-04 (148)/5	No	No	Yes/ 2021-01-04 (148)/5	Yes/ 2021-01-04 (148)/5	No	No
Subject ID: US3312024; Age (Year): 34; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
No	No	No	No	Yes/ 2020-09-08 (29)/4	No	No	Yes/ 2020-09-08 (29)/4
Subject ID: US3312053; Age (Year): 20; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2021-01-08 (150)/5	Yes/ 2021-01-08 (150)/5	No	No	Yes/ 2021-01-08 (150)/5	Yes/ 2021-01-08 (150)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312056; Age (Year): 26; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (29)/4	No	No	Yes/ 2020-09-09 (29)/4
Subject ID: US3312068; Age (Year): 21; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/							
Yes/ 2020-08-25 (13)/2	Yes/ 2020-08-25 (13)/2	No	No	Yes/ 2020-08-25 (13)/2	Yes/ 2020-08-25 (13)/2	No	No
Subject ID: US3312086; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2021-01-14 (154)/5	Yes/ 2021-01-14 (154)/5	No	No	Yes/ 2021-01-14 (154)/5	Yes/ 2021-01-14 (154)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312095; Age (Year): 23; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-21							
Yes/ 2020-12-10 (116)/5	Yes/ 2020-12-10 (116)/5	No	No	Yes/ 2020-12-10 (116)/5	Yes/ 2020-12-10 (116)/5	No	No
Subject ID: US3312110; Age (Year): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-12-29 (135)/5	Yes/ 2020-12-29 (135)/5	No	No	Yes/ 2020-12-29 (135)/5	Yes/ 2020-12-29 (135)/5	No	No
Subject ID: US3312130; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-18							
Yes/ 2020-12-16 (121)/5	Yes/ 2020-12-16 (121)/5	No	No	Yes/ 2020-12-16 (121)/5	Yes/ 2020-12-16 (121)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312235; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-11-09 (78)/5	Yes/ 2020-11-09 (78)/5	No	No	Yes/ 2020-11-09 (78)/5	Yes/ 2020-11-09 (78)/5	No	No
Subject ID: US3312296; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-10-28 (64)/5	Yes/ 2020-10-28 (64)/5	No	No	Yes/ 2020-10-28 (64)/5	Yes/ 2020-10-28 (64)/5	No	No
Subject ID: US3312307; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-12-08 (105)/5	Yes/ 2020-12-08 (105)/5	No	No	Yes/ 2020-12-08 (105)/5	Yes/ 2020-12-08 (105)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3312330; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-23							
Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	Yes/ 2021-01-05 (132)/5	Yes/ 2021-01-05 (132)/5	Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	No	No
Subject ID: US3312342; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	No	No	Yes/ 2020-12-14 (110)/5	Yes/ 2020-12-14 (110)/5	No	No
Subject ID: US3312356; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/ 2021-01-18 (144)/5	Yes/ 2021-01-18 (144)/5	No	No	Yes/ 2021-01-18 (144)/5	Yes/ 2021-01-18 (144)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312388; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2020-12-22 (114)/5	Yes/ 2020-12-22 (114)/5	No	No	Yes/ 2020-12-22 (114)/5	Yes/ 2020-12-22 (114)/5	No	No
Subject ID: US3312402; Age (Year): 19; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 37.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2020-10-23 (54)/5	Yes/ 2020-10-23 (54)/5	No	No	Yes/ 2020-10-23 (54)/5	Yes/ 2020-10-23 (54)/5	No	No
Subject ID: US3312437; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-12-28 (119)/5	Yes/ 2020-12-28 (119)/5	No	No	Yes/ 2020-12-28 (119)/5	Yes/ 2020-12-28 (119)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312439; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2021-01-27 (149)/5	Yes/ 2021-01-27 (149)/5	No	No	Yes/ 2021-01-27 (149)/5	Yes/ 2021-01-27 (149)/5	No	No
Subject ID: US3312548; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/							
Yes/ 2020-10-03 (26)/3	Yes/ 2020-10-07 (30)/3	No	No	Yes/ 2020-10-07 (30)/3	Yes/ 2020-10-07 (30)/3	No	No
Subject ID: US3312581; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2020-12-01 (84)/5	Yes/ 2020-12-01 (84)/5	No	No	Yes/ 2020-12-01 (84)/5	Yes/ 2020-12-01 (84)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312587; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/							
Yes/ 2020-10-07 (29)/3	Yes/ 2020-10-07 (29)/3	No	No	Yes/ 2020-10-07 (29)/3	Yes/ 2020-10-07 (29)/3	No	No
Subject ID: US3312605; Age (Year): 24; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
Yes/ 2020-10-27 (48)/5	Yes/ 2020-10-22 (43)/5	Yes/ 2020-10-27 (48)/5	No	Yes/ 2020-10-22 (43)/5	Yes/ 2020-10-22 (43)/5	No	No
Subject ID: US3312608; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
Yes/ 2020-11-19 (71)/5	Yes/ 2020-11-19 (71)/5	No	No	Yes/ 2020-11-19 (71)/5	Yes/ 2020-11-19 (71)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3312622; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-09							
Yes/ 2020-10-23 (43)/5	Yes/ 2020-10-23 (43)/5	No	No	Yes/ 2020-10-23 (43)/5	Yes/ 2020-10-23 (43)/5	No	No
Subject ID: US3312623; Age (Year): 31; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-13							
Yes/ 2020-12-15 (96)/5	Yes/ 2020-12-15 (96)/5	No	No	Yes/ 2020-12-15 (96)/5	Yes/ 2020-12-15 (96)/5	No	No
Subject ID: US3322006; Age (Year): 50; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/							
Yes/ 2020-09-14 (29)/3	Yes/ 2020-09-14 (29)/3	Yes/ 2020-09-17 (32)/3	Yes/ 2020-09-17 (32)/3	Yes/ 2020-09-14 (29)/3	Yes/ 2020-09-14 (29)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3322061; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/							
No	No	No	No	Yes/ 2020-09-11 (22)/3	Yes/ 2020-09-11 (22)/3	No	No
Subject ID: US3322064; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-23							
Yes/ 2020-12-28 (130)/5	Yes/ 2020-12-28 (130)/5	No	No	Yes/ 2020-12-28 (130)/5	Yes/ 2020-12-28 (130)/5	No	No
Subject ID: US3322123; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2021-01-20 (147)/5	Yes/ 2021-01-20 (147)/5	No	No	Yes/ 2021-01-20 (147)/5	Yes/ 2021-01-20 (147)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3322144; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
No	No	No	No	Yes/ 2020-11-24 (86)/5	Yes/ 2020-11-24 (86)/5	No	No
Subject ID: US3322204; Age (Year): 37; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-01							
Yes/ 2020-12-22 (111)/5	Yes/ 2020-12-22 (111)/5	No	No	Yes/ 2020-12-22 (111)/5	Yes/ 2020-12-22 (111)/5	No	No
Subject ID: US3322239; Age (Year): 27; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-09							
No	No	No	No	Yes/ 2020-10-23 (46)/5	Yes/ 2020-10-23 (46)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3322242; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-08							
No	No	No	No	Yes/ 2021-01-11 (126)/5	No	No	Yes/ 2021-01-11 (126)/5
Subject ID: US3322256; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
Yes/ 2020-12-28 (112)/5	Yes/ 2020-12-28 (112)/5	No	No	Yes/ 2020-12-28 (112)/5	Yes/ 2020-12-28 (112)/5	No	No
Subject ID: US3322296; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-09							
Yes/ 2020-12-28 (110)/5	Yes/ 2020-12-28 (110)/5	No	No	Yes/ 2020-12-28 (110)/5	Yes/ 2020-12-28 (110)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3322301; Age (Year): 25; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 22.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
Yes/ 2020-12-10 (92)/5	Yes/ 2020-12-10 (92)/5	No	No	Yes/ 2020-12-10 (92)/5	Yes/ 2020-12-10 (92)/5	No	No
Subject ID: US3322323; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-15							
Yes/ 2020-12-29 (110)/5	Yes/ 2020-12-29 (110)/5	No	No	Yes/ 2020-12-29 (110)/5	Yes/ 2020-12-29 (110)/5	No	No
Subject ID: US3322347; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-13							
Yes/ 2020-10-27 (43)/5	Yes/ 2020-10-27 (43)/5	No	No	Yes/ 2020-10-27 (43)/5	Yes/ 2020-10-27 (43)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*	COVID-19*	COVID-19*	COVID-19*	COVID-19*	COVID-19*	COVID-19	COVID-19
Subject ID: US3322365; Age (Year): 53; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-20							
Yes/ 2020-12-03 (78)/5	Yes/ 2020-12-03 (78)/5	No	No	Yes/ 2020-12-03 (78)/5	Yes/ 2020-12-03 (78)/5	No	No
Subject ID: US3322388; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-28/2020-10-26							
Yes/ 2020-12-21 (85)/5	Yes/ 2020-12-21 (85)/5	Yes/ 2020-12-22 (86)/5	Yes/ 2020-12-22 (86)/5	Yes/ 2020-12-21 (85)/5	Yes/ 2020-12-21 (85)/5	No	No
Subject ID: US3322400; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-18							
Yes/ 2020-11-30 (55)/4	Yes/ 2020-11-30 (55)/4	No	No	Yes/ 2020-11-30 (55)/4	Yes/ 2020-11-30 (55)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3322406; Age (Year): 36; Sex: M; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-01/2020-10-30							
No	No	No	No	Yes/ 2020-10-30 (30)/4	No	No	Yes/ 2020-10-30 (30)/4
Subject ID: US3322409; Age (Year): 31; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-02/2020-11-05							
Yes/ 2020-11-15 (45)/4	Yes/ 2020-11-15 (45)/4	No	No	Yes/ 2020-11-05 (35)/4	Yes/ 2020-11-07 (37)/4	No	Yes/ 2020-11-05 (35)/4
Subject ID: US3322412; Age (Year): 33; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-05/2020-11-05							
Yes/ 2021-01-07 (95)/5	Yes/ 2021-01-07 (95)/5	No	Yes/ 2021-01-16 (104)/5	Yes/ 2021-01-07 (95)/5	Yes/ 2021-01-07 (95)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3332001; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-28							
Yes/ 2020-09-30 (59)/5	Yes/ 2020-09-30 (59)/5	Yes/ 2020-09-30 (59)/5	Yes/ 2020-09-30 (59)/5	Yes/ 2020-09-30 (59)/5	Yes/ 2020-09-30 (59)/5	No	No
Subject ID: US3332068; Age (Year): 44; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-22							
Yes/ 2021-01-18 (144)/5	Yes/ 2021-01-18 (144)/5	No	No	Yes/ 2021-01-18 (144)/5	Yes/ 2021-01-18 (144)/5	No	No
Subject ID: US3332097; Age (Year): 42; Sex: F; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 44.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-12/2020-11-06							
No	No	No	No	Yes/ 2020-11-06 (26)/4	No	No	Yes/ 2020-11-06 (26)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3332101; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-16/2020-11-13							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2021-01-07	2021-01-07	2021-01-26	2021-01-26	2021-01-07	2021-01-07		
(84)/5	(84)/5	(103)/5	(103)/5	(84)/5	(84)/5		
Subject ID: US3342019; Age (Year): 23; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 43.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-24	2020-11-24			2020-11-24	2020-11-24		
(106)/5	(106)/5			(106)/5	(106)/5		
Subject ID: US3342025; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-15							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-12-23	2020-12-23			2020-12-23	2020-12-23		
(135)/5	(135)/5			(135)/5	(135)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3342026; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-15							
Yes/ 2020-12-28 (140)/5	Yes/ 2020-12-28 (140)/5	No	No	Yes/ 2020-12-28 (140)/5	Yes/ 2020-12-28 (140)/5	No	No
Subject ID: US3342037; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-15							
No	No	No	No	Yes/ 2021-01-24 (166)/5	No	No	No
Subject ID: US3342046; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-16							
Yes/ 2020-11-20 (100)/5	Yes/ 2020-11-20 (100)/5	Yes/ 2020-11-21 (101)/5	Yes/ 2020-11-21 (101)/5	Yes/ 2020-11-20 (100)/5	Yes/ 2020-11-20 (100)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3342048; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-16							
Yes/ 2021-01-12 (153)/5	Yes/ 2021-01-12 (153)/5	No	No	Yes/ 2021-01-12 (153)/5	Yes/ 2021-01-12 (153)/5	No	No
Subject ID: US3342112; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-18							
No	No	No	No	Yes/ 2020-10-16 (59)/5	No	No	Yes/ 2020-10-16 (59)/5
Subject ID: US3342131; Age (Year): 31; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 44.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-24							
Yes/ 2020-12-01 (104)/5	Yes/ 2020-12-01 (104)/5	No	No	Yes/ 2020-12-01 (104)/5	Yes/ 2020-12-01 (104)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3342132; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-21							
No	No	No	No	Yes/ 2021-01-26 (160)/5	Yes/ 2021-01-26 (160)/5	No	No
Subject ID: US3342146; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-25							
Yes/ 2020-11-11 (78)/5	Yes/ 2020-11-11 (78)/5	No	No	Yes/ 2020-11-11 (78)/5	Yes/ 2020-11-11 (78)/5	No	No
Subject ID: US3342152; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/ 2020-12-30 (125)/5	Yes/ 2020-12-29 (124)/5	No	No	Yes/ 2020-12-29 (124)/5	Yes/ 2020-12-29 (124)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3342182; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-15							
Yes/ 2021-01-12 (132)/5	Yes/ 2021-01-12 (132)/5	Yes/ 2021-01-16 (136)/5	Yes/ 2021-01-16 (136)/5	Yes/ 2021-01-12 (132)/5	Yes/ 2021-01-12 (132)/5	No	No
Subject ID: US3342271; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-16							
No	No	No	No	Yes/ 2021-01-05 (110)/5	No	No	No
Subject ID: US3342323; Age (Year): 26; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/							
Yes/ 2020-11-18 (35)/3	Yes/ 2020-11-18 (35)/3	No	No	Yes/ 2020-11-18 (35)/3	Yes/ 2020-11-18 (35)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352071; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-08							
Yes/ 2020-12-09 (119)/5	Yes/ 2020-12-09 (119)/5	No	No	Yes/ 2020-12-09 (119)/5	Yes/ 2020-12-09 (119)/5	No	No
Subject ID: US3352072; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/							
Yes/ 2020-08-21 (9)/2	Yes/ 2020-08-21 (9)/2	No	No	Yes/ 2020-08-21 (9)/2	Yes/ 2020-08-21 (9)/2	No	No
Subject ID: US3352090; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-08							
Yes/ 2020-11-11 (91)/5	Yes/ 2020-11-11 (91)/5	No	No	Yes/ 2020-11-10 (90)/5	Yes/ 2020-11-10 (90)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352187; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-19							
No	No	No	No	Yes/ 2020-12-14 (115)/5	Yes/ 2020-12-14 (115)/5	No	No
Subject ID: US3352188; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-19							
Yes/ 2020-12-16 (117)/5	Yes/ 2020-12-14 (115)/5	No	No	Yes/ 2020-12-14 (115)/5	Yes/ 2020-12-14 (115)/5	No	No
Subject ID: US3352217; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-22							
No	No	No	No	Yes/ 2020-10-20 (60)/5	No	No	Yes/ 2020-10-20 (60)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352245; Age (Year): 47; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-19							
Yes/ 2020-11-08 (76)/5	No	No	No	Yes/ 2020-11-06 (74)/5	Yes/ 2020-11-06 (74)/5	No	No
Subject ID: US3352261; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-23 (91)/5	Yes/ 2020-11-23 (91)/5	No	No	Yes/ 2020-11-23 (91)/5	Yes/ 2020-11-23 (91)/5	No	No
Subject ID: US3352304; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-12-21 (112)/5	Yes/ 2020-12-21 (112)/5	No	No	Yes/ 2020-12-21 (112)/5	Yes/ 2020-12-21 (112)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352307; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-12-21 (112)/5	Yes/ 2020-12-21 (112)/5	No	No	Yes/ 2020-12-21 (112)/5	Yes/ 2020-12-21 (112)/5	No	No
Subject ID: US3352422; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-11-03							
No	No	No	No	Yes/ 2020-11-03 (41)/4	No	No	Yes/ 2020-11-03 (41)/4
Subject ID: US3352445; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-27							
No	No	No	No	Yes/ 2020-11-24 (57)/5	No	No	Yes/ 2020-11-24 (57)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352448; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-27							
No	No	No	No	Yes/ 2021-01-11 (105)/5	Yes/ 2021-01-11 (105)/5	No	No
Subject ID: US3352581; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/							
Yes/ 2020-11-02 (19)/3	Yes/ 2020-11-02 (19)/3	No	No	Yes/ 2020-11-02 (19)/3	Yes/ 2020-11-02 (19)/3	No	No
Subject ID: US3362018; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-11-02 (92)/5	Yes/ 2020-11-02 (92)/5	No	No	Yes/ 2020-11-02 (92)/5	Yes/ 2020-11-02 (92)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3362039; Age (Year): 31; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2021-01-11 (161)/5	Yes/ 2021-01-11 (161)/5	No	No	Yes/ 2021-01-11 (161)/5	Yes/ 2021-01-11 (161)/5	No	No
Subject ID: US3362040; Age (Year): 24; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-08							
Yes/ 2020-11-03 (92)/5	Yes/ 2020-11-03 (92)/5	No	Yes/ 2020-11-07 (96)/5	Yes/ 2020-11-03 (92)/5	Yes/ 2020-11-03 (92)/5	No	No
Subject ID: US3362046; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-08							
Yes/ 2020-12-01 (119)/5	Yes/ 2020-12-01 (119)/5	No	No	Yes/ 2020-12-01 (119)/5	Yes/ 2020-12-01 (119)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3362083; Age (Year): 18; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/							
Yes/ 2020-08-31 (24)/3	Yes/ 2020-08-31 (24)/3	No	No	Yes/ 2020-08-31 (24)/3	Yes/ 2020-08-31 (24)/3	No	No
Subject ID: US3362090; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-08							
No	Yes/ 2020-12-21 (136)/5	No	No	Yes/ 2020-12-12 (127)/5	Yes/ 2020-12-21 (136)/5	No	No
Subject ID: US3362125; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-15							
Yes/ 2020-11-09 (89)/5	Yes/ 2020-11-09 (89)/5	No	No	Yes/ 2020-11-09 (89)/5	Yes/ 2020-11-09 (89)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3362133; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-15							
Yes/ 2021-01-04 (145)/5	Yes/ 2021-01-04 (145)/5	No	No	Yes/ 2021-01-04 (145)/5	Yes/ 2021-01-04 (145)/5	No	No
Subject ID: US3362141; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 52.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-25							
Yes/ 2021-01-07 (147)/5	Yes/ 2021-01-07 (147)/5	No	No	Yes/ 2021-01-07 (147)/5	Yes/ 2021-01-07 (147)/5	No	No
Subject ID: US3362142; Age (Year): 26; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-21							
Yes/ 2020-12-08 (117)/5	Yes/ 2020-12-08 (117)/5	No	No	Yes/ 2020-12-08 (117)/5	Yes/ 2020-12-08 (117)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3362153; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2021-01-06 (120)/5	Yes/ 2021-01-06 (120)/5	No	No	Yes/ 2021-01-06 (120)/5	Yes/ 2021-01-06 (120)/5	No	No
Subject ID: US3362168; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2021-01-05 (142)/5	Yes/ 2021-01-05 (142)/5	No	No	Yes/ 2021-01-05 (142)/5	Yes/ 2021-01-05 (142)/5	No	No
Subject ID: US3362227; Age (Year): 87; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-21							
Yes/ 2021-01-08 (140)/5	Yes/ 2021-01-08 (140)/5	No	No	Yes/ 2021-01-08 (140)/5	Yes/ 2021-01-08 (140)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		COVID-19*		and Severity		of COVID-19*	
Subject ID: US3362252; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-21							
No	No	No	No	Yes/ 2020-10-22 (58)/5	No	No	Yes/ 2020-10-22 (58)/5
Subject ID: US3362281; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 65.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-16							
Yes/ 2020-11-23 (74)/5	Yes/ 2020-11-23 (74)/5	No	No	Yes/ 2020-11-23 (74)/5	Yes/ 2020-11-23 (74)/5	No	No
Subject ID: US3362283; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-13							
Yes/ 2021-01-04 (116)/5	Yes/ 2021-01-04 (116)/5	No	No	Yes/ 2021-01-04 (116)/5	Yes/ 2021-01-04 (116)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3372058; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-16 (132)/5	Yes/ 2020-12-16 (132)/5	No	No	Yes/ 2020-12-16 (132)/5	Yes/ 2020-12-16 (132)/5	No	No
Subject ID: US3372059; Age (Year): 75; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-08							
Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-24 (140)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	No	No
Subject ID: US3372086; Age (Year): 45; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-15							
Yes/ 2021-01-14 (157)/5	Yes/ 2021-01-14 (157)/5	No	No	Yes/ 2021-01-14 (157)/5	Yes/ 2021-01-14 (157)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3372110; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/							
No	No	No	No	Yes/ 2020-09-15 (34)/3	No	No	Yes/ 2020-09-15 (34)/3
Subject ID: US3372138; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-21							
Yes/ 2020-12-29 (135)/5	Yes/ 2020-12-29 (135)/5	No	No	Yes/ 2020-12-29 (135)/5	Yes/ 2020-12-29 (135)/5	No	No
Subject ID: US3372189; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-21							
Yes/ 2020-12-21 (124)/5	Yes/ 2020-12-21 (124)/5	No	No	Yes/ 2020-12-21 (124)/5	Yes/ 2020-12-21 (124)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3372234; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-28							
No	No	No	No	Yes/ 2020-12-22 (120)/5	Yes/ 2020-12-22 (120)/5	No	No
Subject ID: US3372237; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-05 (73)/5	No	No	Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-05 (73)/5	No	No
Subject ID: US3372284; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 53.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-28							
Yes/ 2020-12-03 (98)/5	Yes/ 2020-12-03 (98)/5	No	No	Yes/ 2020-12-03 (98)/5	Yes/ 2020-12-03 (98)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3372290; Age (Year): 19; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-10-02							
Yes/ 2020-11-04 (69)/5	Yes/ 2020-11-04 (69)/5	No	No	Yes/ 2020-11-04 (69)/5	Yes/ 2020-11-04 (69)/5	No	No
Subject ID: US3372390; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-15							
Yes/ 2020-12-14 (96)/5	Yes/ 2020-12-14 (96)/5	No	No	Yes/ 2020-12-14 (96)/5	Yes/ 2020-12-14 (96)/5	No	No
Subject ID: US3372472; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-05							
No	No	No	No	Yes/ 2020-12-03 (57)/5	No	No	Yes/ 2020-12-03 (57)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection				
COVID-19*		COVID-19*	Severe	Regardless of	Secondary	Death	Asymptomatic
Based on AC		Based on AC	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
Assessments	COVID-19*	Assessments	COVID-19*	and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3382016; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 39.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-09-08 (29)/4	Yes/ 2020-09-08 (29)/4	No	No	Yes/ 2020-08-29 (19)/3	Yes/ 2020-08-29 (19)/3	No	No
Subject ID: US3382096; Age (Year): 48; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-23							
Yes/ 2021-01-16 (146)/5	Yes/ 2021-01-16 (146)/5	No	No	Yes/ 2021-01-16 (146)/5	Yes/ 2021-01-16 (146)/5	No	No
Subject ID: US3382097; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-28							
Yes/ 2020-12-07 (106)/5	Yes/ 2020-12-07 (106)/5	No	No	Yes/ 2020-12-06 (105)/5	Yes/ 2020-12-06 (105)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3382152; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-02							
Yes/ 2020-11-02 (64)/5	Yes/ 2020-11-02 (64)/5	No	Yes/ 2020-11-04 (66)/5	Yes/ 2020-11-02 (64)/5	Yes/ 2020-11-02 (64)/5	No	No
Subject ID: US3382256; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 45.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-12							
Yes/ 2021-01-07 (118)/5	Yes/ 2021-01-07 (118)/5	No	No	Yes/ 2021-01-07 (118)/5	Yes/ 2021-01-07 (118)/5	No	No
Subject ID: US3382281; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-15							
Yes/ 2021-01-15 (123)/5	Yes/ 2021-01-15 (123)/5	No	No	Yes/ 2021-01-15 (123)/5	Yes/ 2021-01-15 (123)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3392253; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-12							
Yes/ 2020-12-04 (84)/5	Yes/ 2020-11-30 (80)/5	No	No	Yes/ 2020-11-30 (80)/5	Yes/ 2020-11-30 (80)/5	No	No
Subject ID: US3392309; Age (Year): 24; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-15							
Yes/ 2020-12-01 (76)/5	Yes/ 2020-12-01 (76)/5	No	No	Yes/ 2020-12-01 (76)/5	Yes/ 2020-12-01 (76)/5	No	No
Subject ID: US3392311; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-13							
No	No	No	No	Yes/ 2020-11-06 (51)/5	Yes/ 2020-11-06 (51)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3392355; Age (Year): 35; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-02/2020-11-02							
Yes/ 2020-12-28 (88)/5	Yes/ 2020-12-28 (88)/5	No	No	Yes/ 2020-12-28 (88)/5	Yes/ 2020-12-28 (88)/5	No	No
Subject ID: US3402001; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-10-21 (87)/5	Yes/ 2020-10-22 (88)/5	No	No	Yes/ 2020-10-21 (87)/5	Yes/ 2020-10-22 (88)/5	No	No
Subject ID: US3402004; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-12-13 (140)/5	Yes/ 2020-12-13 (140)/5	No	No	Yes/ 2020-12-13 (140)/5	Yes/ 2020-12-13 (140)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3402029; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 56.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-09-30 (66)/5	Yes/ 2020-09-30 (66)/5	Yes/ 2020-10-07 (73)/5	Yes/ 2020-10-05 (71)/5	Yes/ 2020-09-30 (66)/5	Yes/ 2020-09-30 (66)/5	No	No
Subject ID: US3402030; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/2020-08-24							
Yes/ 2020-12-23 (150)/5	Yes/ 2020-12-23 (150)/5	No	No	Yes/ 2020-12-23 (150)/5	Yes/ 2020-12-23 (150)/5	No	No
Subject ID: US3402094; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 45.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
Yes/ 2020-10-02 (66)/5	Yes/ 2020-10-02 (66)/5	No	No	Yes/ 2020-10-02 (66)/5	Yes/ 2020-10-02 (66)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3402155; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-08-31							
No	No	No	No	Yes/ 2020-09-29 (60)/5	No	No	Yes/ 2020-09-29 (60)/5
Subject ID: US3402194; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-02/2020-09-02							
Yes/ 2020-11-13 (104)/5	Yes/ 2020-11-13 (104)/5	Yes/ 2020-11-16 (107)/5	Yes/ 2020-11-16 (107)/5	Yes/ 2020-11-13 (104)/5	Yes/ 2020-11-13 (104)/5	No	No
Subject ID: US3402196; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-12-30 (150)/5	Yes/ 2020-12-30 (150)/5	Yes/ 2020-12-30 (150)/5	Yes/ 2020-12-30 (150)/5	Yes/ 2020-12-29 (149)/5	Yes/ 2020-12-29 (149)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3402328; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-15							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-12-28	2020-12-28			2020-12-28	2020-12-28		
(140)/5	(140)/5			(140)/5	(140)/5		
Subject ID: US3402332; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-15							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2020-12-03	2020-12-03	2020-12-03	2020-12-03	2020-12-03	2020-12-03		
(114)/5	(114)/5	(114)/5	(114)/5	(114)/5	(114)/5		
Subject ID: US3402344; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-17							
No	No	No	No	Yes/	No	No	No
				2020-10-14			
				(61)/5			

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3402358; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-18							
Yes/ 2020-11-19 (97)/5	Yes/ 2020-11-19 (97)/5	No	No	Yes/ 2020-11-19 (97)/5	Yes/ 2020-11-19 (97)/5	No	No
Subject ID: US3402408; Age (Year): 35; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-23							
Yes/ 2020-12-01 (103)/5	Yes/ 2020-12-01 (103)/5	No	No	Yes/ 2020-12-01 (103)/5	Yes/ 2020-12-01 (103)/5	No	No
Subject ID: US3402415; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): ; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-21							
Yes/ 2020-11-09 (80)/5	Yes/ 2020-11-09 (80)/5	No	No	Yes/ 2020-11-09 (80)/5	Yes/ 2020-11-09 (80)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3412012; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
Yes/ 2020-12-28 (153)/5	Yes/ 2020-12-28 (153)/5	Yes/ 2021-01-06 (162)/5	Yes/ 2021-01-06 (162)/5	Yes/ 2020-12-28 (153)/5	Yes/ 2020-12-28 (153)/5	No	No
Subject ID: US3412022; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 49.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-08-26							
Yes/ 2020-11-12 (107)/5	Yes/ 2020-11-12 (107)/5	No	No	Yes/ 2020-11-12 (107)/5	Yes/ 2020-11-12 (107)/5	No	No
Subject ID: US3412108; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-11-25 (115)/5	Yes/ 2020-11-25 (115)/5	No	No	Yes/ 2020-11-25 (115)/5	Yes/ 2020-11-25 (115)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3412141; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2021-01-04 (153)/5	Yes/ 2021-01-04 (153)/5	No	No	Yes/ 2021-01-04 (153)/5	Yes/ 2021-01-04 (153)/5	No	No
Subject ID: US3412208; Age (Year): 75; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-13 (125)/5	Yes/ 2020-12-13 (125)/5	Yes/ 2020-12-10 (122)/5	Yes/ 2020-12-10 (122)/5	No	No
Subject ID: US3412224; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-11-25 (104)/5	Yes/ 2020-11-25 (104)/5	Yes/ 2020-11-30 (109)/5	Yes/ 2020-11-30 (109)/5	Yes/ 2020-11-25 (104)/5	Yes/ 2020-11-25 (104)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3412245; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-22 (131)/5	Yes/ 2020-12-22 (131)/5	No	No	Yes/ 2020-12-22 (131)/5	Yes/ 2020-12-22 (131)/5	No	No
Subject ID: US3412259; Age (Year): 67; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-21							
Yes/ 2020-11-09 (85)/5	Yes/ 2020-11-09 (85)/5	Yes/ 2020-11-11 (87)/5	Yes/ 2020-11-11 (87)/5	Yes/ 2020-11-09 (85)/5	Yes/ 2020-11-09 (85)/5	No	No
Subject ID: US3412270; Age (Year): 77; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
Yes/ 2020-11-03 (78)/5	Yes/ 2020-11-02 (77)/5	No	No	Yes/ 2020-11-02 (77)/5	Yes/ 2020-11-02 (77)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3412300; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 41.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-11-04 (73)/5	Yes/ 2020-11-04 (73)/5	Yes/ 2020-11-10 (79)/5	Yes/ 2020-11-10 (79)/5	Yes/ 2020-11-04 (73)/5	Yes/ 2020-11-04 (73)/5	No	No
Subject ID: US3412304; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-11-05 (74)/5	Yes/ 2020-11-05 (74)/5	Yes/ 2020-11-07 (76)/5	Yes/ 2020-11-07 (76)/5	Yes/ 2020-11-05 (74)/5	Yes/ 2020-11-05 (74)/5	No	No
Subject ID: US3422068; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
No	No	No	No	Yes/ 2020-12-29 (132)/5	Yes/ 2020-12-29 (132)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3422087; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2021-01-04 (134)/5	Yes/ 2021-01-04 (134)/5	No	No	Yes/ 2021-01-04 (134)/5	Yes/ 2021-01-04 (134)/5	No	No
Subject ID: US3422144; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/ 2021-01-06 (132)/5	Yes/ 2021-01-06 (132)/5	No	No	Yes/ 2021-01-06 (132)/5	Yes/ 2021-01-06 (132)/5	No	No
Subject ID: US3422149; Age (Year): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2020-10-26 (57)/5	Yes/ 2020-10-26 (57)/5	No	No	Yes/ 2020-10-26 (57)/5	Yes/ 2020-10-26 (57)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3422168; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-11-25 (86)/5	Yes/ 2020-11-25 (86)/5	No	No	Yes/ 2020-11-25 (86)/5	Yes/ 2020-11-25 (86)/5	No	No
Subject ID: US3422201; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-01							
Yes/ 2020-12-14 (103)/5	Yes/ 2020-12-14 (103)/5	No	No	Yes/ 2020-12-14 (103)/5	Yes/ 2020-12-14 (103)/5	No	No
Subject ID: US3422276; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-12							
Yes/ 2020-12-11 (89)/5	Yes/ 2020-12-11 (89)/5	No	No	Yes/ 2020-12-11 (89)/5	Yes/ 2020-12-11 (89)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3422311; Age (Year): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/2020-10-26							
Yes/ 2020-11-02 (34)/4	Yes/ 2020-11-02 (34)/4	No	No	Yes/ 2020-11-02 (34)/4	Yes/ 2020-11-02 (34)/4	No	No
Subject ID: US3432020; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-02							
No	No	No	No	Yes/ 2020-09-02 (27)/4	No	No	Yes/ 2020-09-02 (27)/4
Subject ID: US3432090; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
No	No	No	No	Yes/ 2021-02-08 (182)/5	Yes/ 2021-02-08 (182)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3432126; Age (Year): 25; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-11-16 (89)/5	Yes/ 2020-11-16 (89)/5	No	No	Yes/ 2020-11-12 (85)/5	Yes/ 2020-11-12 (85)/5	No	No
Subject ID: US3432146; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-15 (124)/5	Yes/ 2020-12-15 (124)/5	No	No	Yes/ 2020-12-15 (124)/5	Yes/ 2020-12-15 (124)/5	No	No
Subject ID: US3432216; Age (Year): 39; Sex: M; Race: MULTIPLE; (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-18							
Yes/ 2021-01-09 (143)/5	Yes/ 2021-01-09 (143)/5	No	No	Yes/ 2021-01-09 (143)/5	Yes/ 2021-01-09 (143)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3432266; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-22							
Yes/ 2020-12-28 (127)/5	Yes/ 2020-12-28 (127)/5	No	No	Yes/ 2020-12-28 (127)/5	Yes/ 2020-12-28 (127)/5	No	No
Subject ID: US3432289; Age (Year): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
No	No	No	No	Yes/ 2020-11-09 (77)/5	Yes/ 2020-11-09 (77)/5	No	No
Subject ID: US3432328; Age (Year): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
No	No	No	No	Yes/ 2021-01-16 (143)/5	Yes/ 2021-01-21 (148)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3432344; Age (Year): 77; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/ 2020-10-16 (50)/5	Yes/ 2020-10-14 (48)/5	No	No	Yes/ 2020-10-14 (48)/5	Yes/ 2020-10-14 (48)/5	No	No
Subject ID: US3432373; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
No	No	No	No	Yes/ 2020-09-28 (29)/4	No	No	Yes/ 2020-09-28 (29)/4
Subject ID: US3432387; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-10-01							
Yes/ 2020-11-16 (77)/5	Yes/ 2020-11-16 (77)/5	No	No	Yes/ 2020-11-16 (77)/5	Yes/ 2020-11-16 (77)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3432416; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-01							
Yes/ 2020-12-03 (92)/5	Yes/ 2020-12-03 (92)/5	No	No	Yes/ 2020-12-03 (92)/5	Yes/ 2020-12-03 (92)/5	No	No
Subject ID: US3432424; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
Yes/ 2021-01-05 (124)/5	Yes/ 2021-01-04 (123)/5	No	No	Yes/ 2021-01-04 (123)/5	Yes/ 2021-01-04 (123)/5	No	No
Subject ID: US3432431; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-01							
Yes/ 2020-11-27 (85)/5	Yes/ 2020-11-27 (85)/5	No	No	Yes/ 2020-11-27 (85)/5	Yes/ 2020-11-27 (85)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3432521; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-16							
Yes/ 2020-12-28 (103)/5	Yes/ 2020-12-28 (103)/5	No	No	Yes/ 2020-12-28 (103)/5	Yes/ 2020-12-28 (103)/5	No	No
Subject ID: US3432642; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-19							
Yes/ 2021-01-09 (80)/5	Yes/ 2021-01-09 (80)/5	No	No	Yes/ 2021-01-09 (80)/5	Yes/ 2021-01-09 (80)/5	No	No
Subject ID: US3442051; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-10-25 (67)/5	Yes/ 2020-10-25 (67)/5	No	Yes/ 2021-01-19 (153)/5	Yes/ 2020-10-25 (67)/5	Yes/ 2020-10-25 (67)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3442065; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-11-18 (90)/5	Yes/ 2020-11-18 (90)/5	No	No	Yes/ 2020-11-18 (90)/5	Yes/ 2020-11-18 (90)/5	No	No
Subject ID: US3442069; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-22							
Yes/ 2020-11-06 (78)/5	Yes/ 2020-11-06 (78)/5	No	No	Yes/ 2020-11-06 (78)/5	Yes/ 2020-11-06 (78)/5	No	No
Subject ID: US3442096; Age (Year): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-21							
Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3442131; Age (Year): 44; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
Yes/ 2020-12-28 (116)/5	Yes/ 2020-12-28 (116)/5	No	No	Yes/ 2020-12-28 (116)/5	Yes/ 2020-12-28 (116)/5	No	No
Subject ID: US3442136; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-09							
No	No	No	No	Yes/ 2020-10-09 (26)/4	No	No	Yes/ 2020-10-09 (26)/4
Subject ID: US3442163; Age (Year): 78; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-14							
Yes/ 2020-10-21 (37)/4	Yes/ 2020-10-21 (37)/4	No	Yes/ 2020-10-28 (44)/5	Yes/ 2020-10-21 (37)/4	Yes/ 2020-10-21 (37)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3442171; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-15							
No	No	No	No	Yes/ 2020-12-14 (90)/5	Yes/ 2020-12-14 (90)/5	No	No
Subject ID: US3442173; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-15							
Yes/ 2020-12-07 (83)/5	Yes/ 2020-12-07 (83)/5	Yes/ 2020-12-12 (88)/5	Yes/ 2020-12-12 (88)/5	Yes/ 2020-12-07 (83)/5	Yes/ 2020-12-07 (83)/5	No	No
Subject ID: US3452035; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-08-24							
Yes/ 2020-11-04 (98)/5	Yes/ 2020-11-04 (98)/5	No	No	Yes/ 2020-11-04 (98)/5	Yes/ 2020-11-04 (98)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3452041; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-08-24							
Yes/ 2020-12-09 (133)/5	Yes/ 2020-12-10 (134)/5	No	No	Yes/ 2020-12-10 (134)/5	Yes/ 2020-12-10 (134)/5	No	No
Subject ID: US3452102; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-08-28							
Yes/ 2021-01-12 (165)/5	Yes/ 2021-01-12 (165)/5	No	No	Yes/ 2021-01-12 (165)/5	Yes/ 2021-01-12 (165)/5	No	No
Subject ID: US3452115; Age (Year): 22; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-08-29							
No	No	No	No	Yes/ 2020-11-23 (115)/5	Yes/ 2020-11-23 (115)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*		Based on AC Assessments	Severe COVID-19*				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3452122; Age (Year): 23; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-09-03							
No	No	No	No	Yes/ 2020-10-02 (61)/5	No	No	Yes/ 2020-10-02 (61)/5
Subject ID: US3452130; Age (Year): 30; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-11-17 (107)/5	Yes/ 2020-11-17 (107)/5	No	No	Yes/ 2020-11-17 (107)/5	Yes/ 2020-11-17 (107)/5	No	No
Subject ID: US3452168; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 39.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-02							
Yes/ 2020-12-03 (122)/5	Yes/ 2020-12-03 (122)/5	No	No	Yes/ 2020-12-03 (122)/5	Yes/ 2020-12-03 (122)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3452203; Age (Year): 80; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-03							
Yes/ 2020-11-17 (106)/5	Yes/ 2020-11-17 (106)/5	Yes/ 2020-11-18 (107)/5	Yes/ 2020-11-17 (106)/5	Yes/ 2020-11-17 (106)/5	Yes/ 2020-11-17 (106)/5	No	No
Subject ID: US3452212; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-08-31							
Yes/ 2020-12-01 (120)/5	Yes/ 2020-12-01 (120)/5	No	No	Yes/ 2020-11-30 (119)/5	Yes/ 2020-11-30 (119)/5	No	No
Subject ID: US3452232; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-08							
Yes/ 2020-12-15 (133)/5	Yes/ 2020-12-15 (133)/5	Yes/ 2020-12-23 (141)/5	Yes/ 2020-12-23 (141)/5	Yes/ 2020-12-15 (133)/5	Yes/ 2020-12-15 (133)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3452278; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-09							
Yes/ 2020-11-30 (117)/5	Yes/ 2020-11-30 (117)/5	No	No	Yes/ 2020-11-30 (117)/5	Yes/ 2020-11-30 (117)/5	No	No
Subject ID: US3452282; Age (Year): 37; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
No	No	No	No	Yes/ 2020-09-03 (29)/4	No	No	Yes/ 2020-09-03 (29)/4
Subject ID: US3452331; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-03							
Yes/ 2020-10-26 (81)/5	Yes/ 2020-10-26 (81)/5	No	No	Yes/ 2020-10-26 (81)/5	Yes/ 2020-10-26 (81)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3452332; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-03							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2020-10-27	2020-10-27	2020-10-31	2020-10-31	2020-10-26	2020-10-26		
(82)/5	(82)/5	(86)/5	(86)/5	(81)/5	(81)/5		
Subject ID: US3452369; Age (Year): 42; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-14							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-16	2020-11-16			2020-11-16	2020-11-16		
(62)/5	(62)/5			(62)/5	(62)/5		
Subject ID: US3462051; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-19	2020-11-19			2020-11-19	2020-11-19		
(106)/5	(106)/5			(106)/5	(106)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3462161; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 50.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-17							
Yes/ 2020-12-14 (124)/5	Yes/ 2020-12-14 (124)/5	No	No	Yes/ 2020-12-14 (124)/5	Yes/ 2020-12-14 (124)/5	No	No
Subject ID: US3462180; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-11-06 (85)/5	Yes/ 2020-11-06 (85)/5	No	No	Yes/ 2020-11-06 (85)/5	Yes/ 2020-11-06 (85)/5	No	No
Subject ID: US3462181; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-10							
Yes/ 2020-11-02 (81)/5	Yes/ 2020-11-02 (81)/5	No	No	Yes/ 2020-11-02 (81)/5	Yes/ 2020-11-02 (81)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3462299; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-23							
Yes/2020-11-16 (85)/5	Yes/2020-11-16 (85)/5	No	No	Yes/2020-11-16 (85)/5	Yes/2020-11-16 (85)/5	No	No
Subject ID: US3462374; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/2021-01-04 (131)/5	Yes/2021-01-04 (131)/5	Yes/2021-01-08 (135)/5	Yes/2021-01-08 (135)/5	Yes/2021-01-04 (131)/5	Yes/2021-01-04 (131)/5	No	No
Subject ID: US3462375; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/2021-01-08 (135)/5	Yes/2021-01-08 (135)/5	No	No	Yes/2021-01-08 (135)/5	Yes/2021-01-08 (135)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3472020; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-07							
Yes/ 2020-12-04 (88)/5	Yes/ 2020-12-04 (88)/5	No	No	Yes/ 2020-12-04 (88)/5	Yes/ 2020-12-04 (88)/5	No	No
Subject ID: US3472068; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-20							
Yes/ 2021-01-11 (112)/5	Yes/ 2021-01-11 (112)/5	No	No	Yes/ 2021-01-11 (112)/5	Yes/ 2021-01-11 (112)/5	No	No
Subject ID: US3472096; Age (Year): 42; Sex: M; Race: MULTIPLE; (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/							
Yes/ 2020-11-10 (35)/3	Yes/ 2020-11-10 (35)/3	No	No	Yes/ 2020-11-10 (35)/3	Yes/ 2020-11-10 (35)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*		Infection			
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3472099; Age (Year): 35; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 32.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-11							
Yes/ 2020-12-28 (82)/5	Yes/ 2020-12-27 (81)/5	No	No	Yes/ 2020-12-22 (76)/5	Yes/ 2020-12-27 (81)/5	No	No
Subject ID: US3472130; Age (Year): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 35.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/							
Yes/ 2020-11-09 (18)/3	Yes/ 2020-11-09 (18)/3	Yes/ 2020-11-12 (21)/3	Yes/ 2020-11-12 (21)/3	Yes/ 2020-11-09 (18)/3	Yes/ 2020-11-09 (18)/3	No	No
Subject ID: US3482036; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-10							
Yes/ 2020-12-27 (137)/5	Yes/ 2020-12-27 (137)/5	No	No	Yes/ 2020-12-22 (132)/5	Yes/ 2020-12-22 (132)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3482045; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-14							
Yes/ 2020-11-24 (104)/5	Yes/ 2020-11-24 (104)/5	No	No	Yes/ 2020-11-24 (104)/5	Yes/ 2020-11-24 (104)/5	No	No
Subject ID: US3482076; Age (Year): 43; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-16							
No	No	No	No	Yes/ 2021-01-04 (140)/5	Yes/ 2021-01-04 (140)/5	No	No
Subject ID: US3482094; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-22							
Yes/ 2020-12-17 (120)/5	Yes/ 2020-12-17 (120)/5	Yes/ 2020-12-25 (128)/5	Yes/ 2020-12-25 (128)/5	Yes/ 2020-12-17 (120)/5	Yes/ 2020-12-17 (120)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3482121; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-11-16 (85)/5	Yes/ 2020-11-16 (85)/5	No	No	Yes/ 2020-11-16 (85)/5	Yes/ 2020-11-16 (85)/5	No	No
Subject ID: US3482187; Age (Year): 58; Sex: F; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2021-01-05 (127)/5	Yes/ 2021-01-05 (127)/5	No	No	Yes/ 2021-01-05 (127)/5	Yes/ 2021-01-05 (127)/5	No	No
Subject ID: US3482286; Age (Year): 52; Sex: M; Race: MULTIPLE; (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-12							
Yes/ 2021-01-08 (88)/5	Yes/ 2021-01-08 (88)/5	Yes/ 2021-01-08 (88)/5	Yes/ 2021-01-08 (88)/5	Yes/ 2021-01-08 (88)/5	Yes/ 2021-01-08 (88)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3492071; Age (Year): 49; Sex: M; Race: ASIAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-05							
Yes/ 2020-11-16 (74)/5	Yes/ 2020-11-16 (74)/5	No	No	Yes/ 2020-11-16 (74)/5	Yes/ 2020-11-16 (74)/5	No	No
Subject ID: US3492115; Age (Year): 56; Sex: M; Race: OTHER: HISPANIC/LATINO; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-12							
No	No	No	No	Yes/ 2021-01-21 (134)/5	Yes/ 2021-01-25 (138)/5	No	No
Subject ID: US3492117; Age (Year): 61; Sex: F; Race: OTHER: HISPANIC; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/							
Yes/ 2020-09-23 (14)/2	Yes/ 2020-09-23 (14)/2	No	No	Yes/ 2020-09-23 (14)/2	Yes/ 2020-09-23 (14)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection		Death	Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3492142; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 30.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-20							
Yes/ 2020-12-02 (82)/5	Yes/ 2020-12-02 (82)/5	No	No	Yes/ 2020-12-02 (82)/5	Yes/ 2020-12-02 (82)/5	No	No
Subject ID: US3492213; Age (Year): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-19/2020-10-19							
No	No	No	No	Yes/ 2020-11-17 (60)/5	No	No	Yes/ 2020-11-17 (60)/5
Subject ID: US3492242; Age (Year): 29; Sex: M; Race: MULTIPLE: (b) (6)							
(b) (6)		Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 68.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/					
Yes/ 2020-10-05 (13)/2	Yes/ 2020-10-05 (13)/2	No	No	Yes/ 2020-10-05 (13)/2	Yes/ 2020-10-05 (13)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3492278; Age (Year): 26; Sex: F; Race: OTHER; LATINA; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/2020-11-04							
Yes/ 2021-01-19 (112)/5	Yes/ 2021-01-19 (112)/5	No	No	Yes/ 2021-01-19 (112)/5	Yes/ 2021-01-19 (112)/5	No	No
Subject ID: US3492299; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/							
Yes/ 2020-11-20 (39)/3	Yes/ 2020-11-20 (39)/3	No	No	Yes/ 2020-11-20 (39)/3	Yes/ 2020-11-20 (39)/3	No	No
Subject ID: US3502076; Age (Year): 72; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-11-24 (85)/5	Yes/ 2020-11-24 (85)/5	No	No	Yes/ 2020-11-24 (85)/5	Yes/ 2020-11-24 (85)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3502086; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-28							
Yes/ 2020-11-30 (90)/5	Yes/ 2020-11-30 (90)/5	No	No	Yes/ 2020-11-30 (90)/5	Yes/ 2020-11-30 (90)/5	No	No
Subject ID: US3512116; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-11-13 (85)/5	Yes/ 2020-11-13 (85)/5	No	No	Yes/ 2020-11-13 (85)/5	Yes/ 2020-11-13 (85)/5	No	No
Subject ID: US3512141; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/							
Yes/ 2020-12-29 (126)/3	Yes/ 2020-12-29 (126)/3	No	No	Yes/ 2020-12-29 (126)/3	Yes/ 2020-12-29 (126)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3512229; Age (Year): 50; Sex: F; Race: MULTIPLE: (b) (6) NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-05/2020-10-07							
No	No	No	No	Yes/ 2020-11-04 (61)/5	No	No	Yes/ 2020-11-04 (61)/5
Subject ID: US3512242; Age (Year): 20; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2021-01-11 (125)/5	Yes/ 2021-01-11 (125)/5	No	No	Yes/ 2021-01-11 (125)/5	Yes/ 2021-01-11 (125)/5	No	No
Subject ID: US3512248; Age (Year): 76; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
No	No	No	No	Yes/ 2020-10-08 (29)/4	No	No	Yes/ 2020-10-08 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]								
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection		Secondary Definition of COVID-19*		Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection	
Subject ID: US3512263; Age (Year): 46; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-14								
Yes/ 2020-11-20 (70)/5	Yes/ 2020-11-20 (70)/5	No	No	Yes/ 2020-11-20 (70)/5	Yes/ 2020-11-20 (70)/5	No	No	
Subject ID: US3512280; Age (Year): 61; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-28								
No	No	No	No	Yes/ 2020-11-25 (64)/5	No	No	Yes/ 2020-11-25 (64)/5	
Subject ID: US3522042; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/								
Yes/ 2020-08-22 (16)/3	Yes/ 2020-08-24 (18)/3	No	No	Yes/ 2020-08-24 (18)/3	Yes/ 2020-08-24 (18)/3	No	No	

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3522081; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-11							
No	No	No	No	Yes/ 2020-09-11 (32)/4	No	No	Yes/ 2020-09-11 (32)/4
Subject ID: US3522105; Age (Year): 37; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-08							
Yes/ 2020-10-26 (76)/5	Yes/ 2020-10-26 (76)/5	No	No	Yes/ 2020-10-26 (76)/5	Yes/ 2020-10-26 (76)/5	No	No
Subject ID: US3522127; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-14 (123)/5	Yes/ 2020-12-14 (123)/5	No	No	Yes/ 2020-12-14 (123)/5	Yes/ 2020-12-14 (123)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3522218; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-11-17 (91)/5	Yes/ 2020-11-19 (93)/5	No	No	Yes/ 2020-11-19 (93)/5	Yes/ 2020-11-19 (93)/5	No	No
Subject ID: US3522248; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-16							
Yes/ 2020-12-30 (133)/5	Yes/ 2020-12-30 (133)/5	No	No	Yes/ 2020-12-30 (133)/5	Yes/ 2020-12-30 (133)/5	No	No
Subject ID: US3522297; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: UNKNOWN; BMI (kg/m ²): 30.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/							
Yes/ 2020-09-18 (29)/3	Yes/ 2020-09-18 (29)/3	No	No	Yes/ 2020-09-18 (29)/3	Yes/ 2020-09-18 (29)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]									
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19* Death Caused by COVID-19		Asymptomatic SARS-CoV-2 Infection	
COVID-19*		COVID-19*		(b) (6)		Ethnicity: NOT HISPANIC OR LATINO;			
Subject ID: US3522307; Age (Year): 31; Sex: M; Race: OTHER: (b) (6)								Ethnicity: NOT HISPANIC OR LATINO;	
BMI (kg/m²): 20.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21									
Yes/ 2020-09-23 (31)/4	Yes/ 2020-09-23 (31)/4	No	No	Yes/ 2020-09-23 (31)/4	Yes/ 2020-09-23 (31)/4	No	No		
Subject ID: US3522336; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22									
No	No	No	No	Yes/ 2020-12-21 (119)/5	Yes/ 2020-12-21 (119)/5	No	No		
Subject ID: US3522460; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 39.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-05									
Yes/ 2020-12-29 (121)/5	Yes/ 2020-12-29 (121)/5	No	No	Yes/ 2020-12-29 (121)/5	Yes/ 2020-12-29 (121)/5	No	No		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3522583; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-09							
No	No	No	No	Yes/ 2020-11-06 (64)/5	No	No	Yes/ 2020-11-06 (64)/5
Subject ID: US3522672; Age (Year): 28; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-14							
Yes/ 2020-12-15 (96)/5	Yes/ 2020-12-15 (96)/5	No	No	Yes/ 2020-12-15 (96)/5	Yes/ 2020-12-15 (96)/5	No	No
Subject ID: US3522674; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-12							
No	No	No	No	Yes/ 2020-10-12 (29)/4	No	No	Yes/ 2020-10-12 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3532103; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-23							
Yes/ 2020-11-27 (99)/5	Yes/ 2020-11-27 (99)/5	No	No	Yes/ 2020-11-27 (99)/5	Yes/ 2020-11-27 (99)/5	No	No
Subject ID: US3532163; Age (Year): 31; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-22							
Yes/ 2020-11-02 (69)/5	Yes/ 2020-11-02 (69)/5	No	No	Yes/ 2020-11-02 (69)/5	Yes/ 2020-11-02 (69)/5	No	No
Subject ID: US3532165; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-11-02 (68)/5	Yes/ 2020-11-02 (68)/5	No	No	Yes/ 2020-11-02 (68)/5	Yes/ 2020-11-02 (68)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3532246; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
Yes/ 2020-10-28 (51)/5	Yes/ 2020-10-28 (51)/5	No	No	Yes/ 2020-10-28 (51)/5	Yes/ 2020-10-28 (51)/5	No	No
Subject ID: US3532251; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
Yes/ 2020-12-02 (86)/5	Yes/ 2020-12-02 (86)/5	No	No	Yes/ 2020-12-02 (86)/5	Yes/ 2020-12-02 (86)/5	No	No
Subject ID: US3542019; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
Yes/ 2020-12-25 (130)/5	Yes/ 2020-12-25 (130)/5	No	No	Yes/ 2020-12-25 (130)/5	Yes/ 2020-12-25 (130)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3542030; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 48.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-24							
No	No	No	No	Yes/ 2020-09-24 (36)/4	No	No	Yes/ 2020-09-24 (36)/4
Subject ID: US3542043; Age (Year): 26; Sex: F; Race: MULTIPLE: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/							
Yes/ 2020-09-15 (23)/3	Yes/ 2020-09-15 (23)/3	No	No	Yes/ 2020-09-15 (23)/3	Yes/ 2020-09-15 (23)/3	No	No
Subject ID: US3542123; Age (Year): 51; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-30							
No	No	No	No	Yes/ 2020-10-29 (59)/5	No	No	Yes/ 2020-10-29 (59)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3542153; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-09							
Yes/ 2020-11-16 (74)/5	Yes/ 2020-11-16 (74)/5	No	Yes/ 2020-11-28 (86)/5	Yes/ 2020-11-16 (74)/5	Yes/ 2020-11-16 (74)/5	No	No
Subject ID: US3542339; Age (Year): 22; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-13							
Yes/ 2021-01-19 (99)/5	Yes/ 2021-01-19 (99)/5	No	No	Yes/ 2021-01-19 (99)/5	Yes/ 2021-01-19 (99)/5	No	No
Subject ID: US3552002; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-07							
Yes/ 2020-09-21 (43)/5	Yes/ 2020-09-21 (43)/5	No	No	Yes/ 2020-09-21 (43)/5	Yes/ 2020-09-21 (43)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3552020; Age (Year): 76; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-12-10 (121)/5	Yes/ 2020-12-10 (121)/5	No	No	Yes/ 2020-12-10 (121)/5	Yes/ 2020-12-10 (121)/5	No	No
Subject ID: US3552023; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-09							
Yes/ 2020-11-24 (104)/5	Yes/ 2020-11-24 (104)/5	No	No	Yes/ 2020-11-24 (104)/5	Yes/ 2020-11-24 (104)/5	No	No
Subject ID: US3552048; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-11							
Yes/ 2020-11-17 (93)/5	Yes/ 2020-11-17 (93)/5	No	No	Yes/ 2020-11-17 (93)/5	Yes/ 2020-11-17 (93)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3552153; Age (Year): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-12-22 (121)/5	Yes/ 2020-12-22 (121)/5	No	No	Yes/ 2020-12-22 (121)/5	Yes/ 2020-12-22 (121)/5	No	No
Subject ID: US3552232; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-29/							
Yes/ 2021-01-26 (151)/3	Yes/ 2021-01-26 (151)/3	No	No	Yes/ 2021-01-26 (151)/3	Yes/ 2021-01-26 (151)/3	No	No
Subject ID: US3552269; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-11-12 (73)/5	Yes/ 2020-11-12 (73)/5	No	No	Yes/ 2020-11-12 (73)/5	Yes/ 2020-11-12 (73)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3552270; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-12-14 (105)/5	Yes/ 2020-12-14 (105)/5	No	No	Yes/ 2020-12-14 (105)/5	Yes/ 2020-12-14 (105)/5	No	No
Subject ID: US3552325; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
Yes/ 2020-12-04 (92)/5	Yes/ 2020-12-04 (92)/5	No	No	Yes/ 2020-12-04 (92)/5	Yes/ 2020-12-04 (92)/5	No	No
Subject ID: US3552423; Age (Year): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-14							
No	No	No	No	Yes/ 2020-11-10 (60)/5	No	No	Yes/ 2020-11-10 (60)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3562015; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2021-01-01 (149)/5	Yes/ 2020-12-31 (148)/5	Yes/ 2021-01-08 (156)/5	Yes/ 2021-01-08 (156)/5	Yes/ 2020-12-31 (148)/5	Yes/ 2020-12-31 (148)/5	No	No
Subject ID: US3562040; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-18							
Yes/ 2020-12-02 (111)/5	Yes/ 2020-12-02 (111)/5	Yes/ 2020-12-08 (117)/5	No	Yes/ 2020-12-02 (111)/5	Yes/ 2020-12-02 (111)/5	No	No
Subject ID: US3562073; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2021-01-18 (148)/5	Yes/ 2021-01-18 (148)/5	No	No	Yes/ 2021-01-18 (148)/5	Yes/ 2021-01-18 (148)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3562076; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-12-18 (116)/5	No	No	No	Yes/ 2020-12-18 (116)/5	Yes/ 2020-12-18 (116)/5	No	No
Subject ID: US3562144; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-09							
Yes/ 2020-12-02 (84)/5	Yes/ 2020-12-01 (83)/5	No	No	Yes/ 2020-11-30 (82)/5	Yes/ 2020-11-30 (82)/5	No	No
Subject ID: US3562175; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-13							
No	No	No	No	Yes/ 2020-10-13 (28)/4	No	No	Yes/ 2020-10-13 (28)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3562177; Age (Year): 33; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-13							
No	No	No	No	Yes/ 2020-11-12 (58)/5	No	No	Yes/ 2020-11-12 (58)/5
Subject ID: US3562218; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 19.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-04							
Yes/ 2020-11-25 (50)/5	Yes/ 2020-11-25 (50)/5	No	No	Yes/ 2020-11-25 (50)/5	Yes/ 2020-11-25 (50)/5	No	No
Subject ID: US3562220; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-05							
Yes/ 2021-01-05 (90)/5	Yes/ 2021-01-05 (90)/5	No	No	Yes/ 2021-01-02 (87)/5	Yes/ 2021-01-02 (87)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3572004; Age (Year): 69; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-12-14 (120)/5	Yes/ 2020-12-14 (120)/5	No	No	Yes/ 2020-12-14 (120)/5	Yes/ 2020-12-14 (120)/5	No	No
Subject ID: US3572036; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-23							
Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-04 (138)/5	No	No	Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-04 (138)/5	No	No
Subject ID: US3572078; Age (Year): 22; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 39.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/							
No	No	No	No	Yes/ 2020-12-21 (120)/3	No	No	Yes/ 2020-12-21 (120)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		COVID-19*		and Severity		of COVID-19*	
Subject ID: US3572086; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-23							
No	No	No	No	Yes/ 2021-01-03 (132)/5	No	Yes/ 2021-02-12 (172)/5	No
Subject ID: US3572156; Age (Year): 19; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-30							
Yes/ 2020-12-11 (102)/5	Yes/ 2020-12-11 (102)/5	No	No	Yes/ 2020-12-11 (102)/5	Yes/ 2020-12-11 (102)/5	No	No
Subject ID: US3572174; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-02							
Yes/ 2020-12-21 (110)/5	Yes/ 2020-12-21 (110)/5	No	No	Yes/ 2020-12-21 (110)/5	Yes/ 2020-12-21 (110)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3572186; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 46.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-05							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-20	2020-11-20			2020-11-20	2020-11-20		
(78)/5	(78)/5			(78)/5	(78)/5		
Subject ID: US3572199; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 23.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-05							
No	Yes/	No	No	Yes/	Yes/	No	No
	2020-12-19			2020-12-19	2020-12-19		
	(107)/5			(107)/5	(107)/5		
Subject ID: US3572201; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 28.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-06							
No	No	No	No	Yes/	Yes/	No	No
				2020-12-15	2020-12-15		
				(103)/5	(103)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3572256; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 52.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-07							
Yes/ 2021-01-06 (119)/5	Yes/ 2021-01-06 (119)/5	No	No	Yes/ 2021-01-06 (119)/5	Yes/ 2021-01-06 (119)/5	No	No
Subject ID: US3572306; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-12							
Yes/ 2021-01-04 (111)/5	Yes/ 2021-01-04 (111)/5	No	No	Yes/ 2021-01-04 (111)/5	Yes/ 2021-01-04 (111)/5	No	No
Subject ID: US3572320; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-21/2020-10-23							
Yes/ 2020-12-22 (93)/5	Yes/ 2020-12-23 (94)/5	No	No	Yes/ 2020-12-22 (93)/5	Yes/ 2020-12-23 (94)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3572323; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-23							
No	No	No	No	Yes/ 2020-12-29 (97)/5	Yes/ 2020-12-29 (97)/5	No	No
Subject ID: US3572324; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-21							
Yes/ 2020-12-31 (101)/5	Yes/ 2020-12-25 (95)/5	Yes/ 2020-12-31 (101)/5	Yes/ 2020-12-25 (95)/5	Yes/ 2020-12-25 (95)/5	Yes/ 2020-12-25 (95)/5	No	No
Subject ID: US3572327; Age (Year): 22; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-25/2020-10-30							
Yes/ 2020-12-10 (77)/5	Yes/ 2020-12-10 (77)/5	No	Yes/ 2020-12-10 (77)/5	Yes/ 2020-12-10 (77)/5	Yes/ 2020-12-10 (77)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3572377; Age (Year): 34; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-11							
No	No	No	No	Yes/ 2020-11-11 (36)/4	No	No	Yes/ 2020-11-11 (36)/4
Subject ID: US3582142; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-09							
Yes/ 2020-12-04 (85)/5	Yes/ 2020-12-04 (85)/5	No	No	Yes/ 2020-12-04 (85)/5	Yes/ 2020-12-04 (85)/5	No	No
Subject ID: US3592014; Age (Year): 44; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-04							
Yes/ 2020-11-13 (101)/5	Yes/ 2020-11-13 (101)/5	No	No	Yes/ 2020-11-13 (101)/5	Yes/ 2020-11-13 (101)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3592053; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-01 (117)/5	No	No	Yes/ 2020-12-01 (117)/5	Yes/ 2020-12-01 (117)/5	No	No
Subject ID: US3592063; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-05							
Yes/ 2021-01-26 (172)/5	Yes/ 2021-01-26 (172)/5	No	No	Yes/ 2021-01-26 (172)/5	Yes/ 2021-01-26 (172)/5	No	No
Subject ID: US3592075; Age (Year): 65; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-08/2020-09-05							
Yes/ 2020-12-28 (143)/5	Yes/ 2020-12-28 (143)/5	Yes/ 2021-01-04 (150)/5	Yes/ 2021-01-04 (150)/5	Yes/ 2020-12-28 (143)/5	Yes/ 2020-12-28 (143)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3592083; Age (Year): 32; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-09/2020-09-06							
Yes/ 2021-01-27 (172)/5	Yes/ 2021-01-27 (172)/5	No	No	Yes/ 2021-01-27 (172)/5	Yes/ 2021-01-27 (172)/5	No	No
Subject ID: US3592084; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 46.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-09/2020-09-06							
Yes/ 2020-11-03 (87)/5	Yes/ 2020-11-03 (87)/5	No	No	Yes/ 2020-11-03 (87)/5	Yes/ 2020-11-03 (87)/5	No	No
Subject ID: US3592115; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
No	No	No	No	Yes/ 2020-09-08 (29)/4	No	No	Yes/ 2020-09-08 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3592117; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-11-06 (88)/5	Yes/ 2020-11-06 (88)/5	No	No	Yes/ 2020-11-06 (88)/5	Yes/ 2020-11-06 (88)/5	No	No
Subject ID: US3592127; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-10							
Yes/ 2020-11-13 (95)/5	Yes/ 2020-11-13 (95)/5	Yes/ 2020-11-14 (96)/5	Yes/ 2020-11-14 (96)/5	Yes/ 2020-11-13 (95)/5	Yes/ 2020-11-13 (95)/5	No	No
Subject ID: US3592132; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2020-10-27 (77)/5	Yes/ 2020-10-27 (77)/5	No	No	Yes/ 2020-10-27 (77)/5	Yes/ 2020-10-27 (77)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3592159; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-22 (131)/5	Yes/ 2020-12-22 (131)/5	No	No	Yes/ 2020-12-22 (131)/5	Yes/ 2020-12-22 (131)/5	No	No
Subject ID: US3592161; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-11-02 (81)/5	Yes/ 2020-11-02 (81)/5	No	No	Yes/ 2020-11-02 (81)/5	Yes/ 2020-11-02 (81)/5	No	No
Subject ID: US3592189; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-12							
Yes/ 2020-11-06 (84)/5	Yes/ 2020-11-06 (84)/5	No	No	Yes/ 2020-11-06 (84)/5	Yes/ 2020-11-06 (84)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3602034; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: UNKNOWN; BMI (kg/m ²): 24.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-09							
Yes/ 2020-10-28 (48)/5	Yes/ 2020-10-28 (48)/5	No	No	Yes/ 2020-10-28 (48)/5	Yes/ 2020-10-28 (48)/5	No	No
Subject ID: US3602038; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-19							
Yes/ 2020-11-09 (57)/5	Yes/ 2020-11-09 (57)/5	No	No	Yes/ 2020-11-09 (57)/5	Yes/ 2020-11-09 (57)/5	No	No
Subject ID: US3602074; Age (Year): 50; Sex: M; Race: ASIAN; Ethnicity: UNKNOWN; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-21/2020-10-19							
Yes/ 2020-12-02 (73)/5	Yes/ 2020-12-02 (73)/5	Yes/ 2020-12-10 (81)/5	Yes/ 2020-12-10 (81)/5	Yes/ 2020-12-02 (73)/5	Yes/ 2020-12-02 (73)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3602111; Age (Year): 36; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/							
Yes/ 2020-10-27 (29)/3	Yes/ 2020-10-27 (29)/3	No	No	Yes/ 2020-10-27 (29)/3	Yes/ 2020-10-27 (29)/3	No	No
Subject ID: US3602116; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/2020-10-29							
Yes/ 2021-01-20 (113)/5	Yes/ 2021-01-20 (113)/5	No	No	Yes/ 2021-01-20 (113)/5	Yes/ 2021-01-20 (113)/5	No	No
Subject ID: US3612031; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-06							
Yes/ 2020-12-28 (110)/5	Yes/ 2020-12-28 (110)/5	Yes/ 2020-12-31 (113)/5	Yes/ 2020-12-31 (113)/5	Yes/ 2020-12-28 (110)/5	Yes/ 2020-12-28 (110)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3612037; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-12							
Yes/ 2020-12-24 (102)/5	Yes/ 2020-12-22 (100)/5	No	No	Yes/ 2020-12-22 (100)/5	Yes/ 2020-12-22 (100)/5	No	No
Subject ID: US3612052; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-25/2020-10-26							
Yes/ 2020-12-18 (85)/5	Yes/ 2020-12-18 (85)/5	No	No	Yes/ 2020-12-18 (85)/5	Yes/ 2020-12-18 (85)/5	No	No
Subject ID: US3612082; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-17							
Yes/ 2020-12-29 (69)/5	Yes/ 2020-12-29 (69)/5	No	No	Yes/ 2020-12-29 (69)/5	Yes/ 2020-12-29 (69)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3622115; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2021-01-13 (136)/5	Yes/ 2021-01-13 (136)/5	No	No	Yes/ 2021-01-13 (136)/5	Yes/ 2021-01-13 (136)/5	No	No
Subject ID: US3622249; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-01/2020-11-02							
Yes/ 2020-12-09 (70)/5	Yes/ 2020-12-14 (75)/5	No	No	Yes/ 2020-12-14 (75)/5	Yes/ 2020-12-14 (75)/5	No	No
Subject ID: US3622257; Age (Year): 62; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-06/2020-11-04							
Yes/ 2020-11-10 (36)/4	Yes/ 2020-11-10 (36)/4	No	No	Yes/ 2020-11-10 (36)/4	Yes/ 2020-11-10 (36)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3622263; Age (Year): 20; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 22.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-10/2020-11-13							
Yes/ 2021-01-04 (87)/5	Yes/ 2021-01-04 (87)/5	No	No	Yes/ 2021-01-04 (87)/5	Yes/ 2021-01-04 (87)/5	No	No
Subject ID: US3632018; Age (Year): 56; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-22							
Yes/ 2020-12-22 (118)/5	Yes/ 2020-12-22 (118)/5	No	No	Yes/ 2020-12-22 (118)/5	Yes/ 2020-12-22 (118)/5	No	No
Subject ID: US3632039; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-30							
Yes/ 2020-12-16 (106)/5	Yes/ 2020-12-16 (106)/5	No	No	Yes/ 2020-12-16 (106)/5	Yes/ 2020-12-16 (106)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3632094; Age (Year): 39; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-12							
Yes/ 2020-11-03 (48)/5	Yes/ 2020-11-03 (48)/5	No	No	Yes/ 2020-11-03 (48)/5	Yes/ 2020-11-03 (48)/5	No	No
Subject ID: US3632107; Age (Year): 46; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-20							
Yes/ 2020-11-24 (62)/5	Yes/ 2020-11-24 (62)/5	Yes/ 2020-12-05 (73)/5	Yes/ 2020-12-05 (73)/5	Yes/ 2020-11-24 (62)/5	Yes/ 2020-11-24 (62)/5	No	No
Subject ID: US3632109; Age (Year): 44; Sex: F; Race: OTHER: MULTIRACIAL; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/2020-10-30							
Yes/ 2020-12-04 (66)/5	Yes/ 2020-12-04 (66)/5	No	No	Yes/ 2020-12-04 (66)/5	Yes/ 2020-12-04 (66)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3632112; Age (Year): 19; Sex: F; Race: MULTIPLE: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-02/2020-11-05							
No	Yes/ 2020-11-12 (42)/4	No	Yes/ 2020-11-16 (46)/4	Yes/ 2020-11-05 (35)/4	Yes/ 2020-11-12 (42)/4	No	Yes/ 2020-11-05 (35)/4
Subject ID: US3632114; Age (Year): 41; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-06/2020-11-06							
Yes/ 2020-12-14 (70)/5	Yes/ 2020-12-14 (70)/5	No	No	Yes/ 2020-12-14 (70)/5	Yes/ 2020-12-14 (70)/5	No	No
Subject ID: US3632116; Age (Year): 37; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-04							
Yes/ 2020-11-30 (55)/5	Yes/ 2020-11-30 (55)/5	No	No	Yes/ 2020-11-30 (55)/5	Yes/ 2020-11-30 (55)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*		Infection			
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3632129; Age (Year): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-14/2020-11-10							
Yes/ 2020-11-12 (30)/4	Yes/ 2020-11-12 (30)/4	No	No	Yes/ 2020-11-12 (30)/4	Yes/ 2020-11-12 (30)/4	No	No
Subject ID: US3632134; Age (Year): 38; Sex: M; Race: ASIAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/2020-11-12							
Yes/ 2020-12-26 (73)/5	Yes/ 2020-12-26 (73)/5	No	No	Yes/ 2020-12-21 (68)/5	Yes/ 2020-12-21 (68)/5	No	No
Subject ID: US3632152; Age (Year): 48; Sex: M; Race: MULTIPLE: (b) (6)							
(b) (6)	Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-18						
Yes/ 2020-12-23 (62)/5	Yes/ 2020-12-23 (62)/5	No	No	Yes/ 2020-12-23 (62)/5	Yes/ 2020-12-23 (62)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*		Infection			
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3632154; Age (Year): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 40.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-19							
Yes/ 2020-12-10 (50)/5	Yes/ 2020-12-10 (50)/5	Yes/ 2020-12-15 (55)/5	Yes/ 2020-12-15 (55)/5	Yes/ 2020-12-10 (50)/5	Yes/ 2020-12-10 (50)/5	No	No
Subject ID: US3642074; Age (Year): 36; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 23.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	No	No	No	Yes/ 2020-11-16 (77)/5	Yes/ 2020-11-16 (77)/5	No	No
Subject ID: US3642086; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 32.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-10-01							
Yes/ 2020-12-22 (112)/5	Yes/ 2020-12-22 (112)/5	No	No	Yes/ 2020-12-22 (112)/5	Yes/ 2020-12-22 (112)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3642152; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-08							
Yes/ 2020-12-01 (84)/5	Yes/ 2020-12-01 (84)/5	No	No	Yes/ 2020-12-01 (84)/5	Yes/ 2020-12-01 (84)/5	No	No
Subject ID: US3642212; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-12							
Yes/ 2020-12-14 (92)/5	Yes/ 2020-12-14 (92)/5	No	No	Yes/ 2020-12-14 (92)/5	Yes/ 2020-12-14 (92)/5	No	No
Subject ID: US3642224; Age (Year): 48; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-17							
Yes/ 2020-12-11 (87)/5	Yes/ 2020-12-11 (87)/5	No	No	Yes/ 2020-12-11 (87)/5	Yes/ 2020-12-11 (87)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3642227; Age (Year): 47; Sex: F; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-20							
Yes/ 2020-11-20 (66)/5	Yes/ 2020-11-20 (66)/5	No	No	Yes/ 2020-11-20 (66)/5	Yes/ 2020-11-20 (66)/5	No	No
Subject ID: US3642229; Age (Year): 46; Sex: M; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-20							
Yes/ 2020-11-18 (64)/5	Yes/ 2020-11-18 (64)/5	No	No	Yes/ 2020-11-16 (62)/5	Yes/ 2020-11-16 (62)/5	No	No
Subject ID: US3642333; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-18							
No	No	No	No	Yes/ 2020-12-19 (60)/5	No	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3642345; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-20							
Yes/ 2020-12-08 (47)/5	Yes/ 2020-12-08 (47)/5	No	No	Yes/ 2020-12-08 (47)/5	Yes/ 2020-12-08 (47)/5	No	No
Subject ID: US3652039; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/							
Yes/ 2020-10-27 (29)/3	Yes/ 2020-10-27 (29)/3	No	No	Yes/ 2020-10-27 (29)/3	Yes/ 2020-10-27 (29)/3	No	No
Subject ID: US3662030; Age (Year): 47; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-07							
Yes/ 2020-12-27 (111)/5	Yes/ 2020-12-27 (111)/5	No	No	Yes/ 2020-12-27 (111)/5	Yes/ 2020-12-27 (111)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3662041; Age (Year): 74; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-05							
Yes/ 2020-12-28 (112)/5	Yes/ 2020-12-28 (112)/5	No	No	Yes/ 2020-12-28 (112)/5	Yes/ 2020-12-28 (112)/5	No	No
Subject ID: US3662098; Age (Year): 32; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 20.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-12							
Yes/ 2020-10-28 (44)/5	Yes/ 2020-10-28 (44)/5	No	No	Yes/ 2020-10-28 (44)/5	Yes/ 2020-10-28 (44)/5	No	No
Subject ID: US3662124; Age (Year): 37; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-21/2020-10-20							
Yes/ 2021-01-06 (108)/5	Yes/ 2021-01-06 (108)/5	No	No	Yes/ 2021-01-06 (108)/5	Yes/ 2021-01-06 (108)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3662143; Age (Year): 51; Sex: F; Race: OTHER: LATINO; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-28							
Yes/ 2021-01-25 (119)/5	Yes/ 2021-01-25 (119)/5	No	No	Yes/ 2021-01-22 (116)/5	Yes/ 2021-01-22 (116)/5	No	No
Subject ID: US3662156; Age (Year): 49; Sex: F; Race: OTHER: LATINA; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-05/2020-11-02							
Yes/ 2020-11-23 (50)/5	Yes/ 2020-11-23 (50)/5	Yes/ 2020-11-28 (55)/5	Yes/ 2020-11-28 (55)/5	Yes/ 2020-11-23 (50)/5	Yes/ 2020-11-23 (50)/5	No	No
Subject ID: US3672018; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-09							
Yes/ 2021-02-04 (182)/5	Yes/ 2021-02-04 (182)/5	No	No	Yes/ 2021-02-04 (182)/5	Yes/ 2021-02-04 (182)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3672061; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2020-11-13 (95)/5	Yes/ 2020-11-11 (93)/5	No	No	Yes/ 2020-11-11 (93)/5	Yes/ 2020-11-11 (93)/5	No	No
Subject ID: US3672068; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-10							
No	No	No	No	Yes/ 2020-09-10 (30)/4	No	No	Yes/ 2020-09-10 (30)/4
Subject ID: US3672097; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/							
Yes/ 2020-09-11 (30)/3	Yes/ 2020-09-11 (30)/3	No	No	Yes/ 2020-09-11 (30)/3	Yes/ 2020-09-11 (30)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3672146; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-15							
Yes/ 2020-11-14 (90)/5	Yes/ 2020-11-12 (88)/5	No	No	Yes/ 2020-11-12 (88)/5	Yes/ 2020-11-12 (88)/5	No	No
Subject ID: US3672230; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-10-18 (60)/5	Yes/ 2020-10-20 (62)/5	No	No	Yes/ 2020-10-20 (62)/5	Yes/ 2020-10-20 (62)/5	No	No
Subject ID: US3672232; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-18							
Yes/ 2020-11-19 (92)/5	Yes/ 2020-11-19 (92)/5	No	No	Yes/ 2020-11-19 (92)/5	Yes/ 2020-11-19 (92)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3672243; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 18.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-24							
Yes/ 2020-11-16 (88)/5	Yes/ 2020-11-16 (88)/5	No	No	Yes/ 2020-11-16 (88)/5	Yes/ 2020-11-16 (88)/5	No	No
Subject ID: US3672244; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-11-12 (84)/5	Yes/ 2020-11-12 (84)/5	No	No	Yes/ 2020-11-12 (84)/5	Yes/ 2020-11-12 (84)/5	No	No
Subject ID: US3672250; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-12-29 (131)/5	Yes/ 2020-12-29 (131)/5	No	No	Yes/ 2020-12-28 (130)/5	Yes/ 2020-12-28 (130)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*		Based on AC Assessments	Severe COVID-19*				
COVID-19*	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3672262; Age (Year): 28; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-21							
No	No	No	No	Yes/ 2020-10-21 (62)/5	No	No	Yes/ 2020-10-21 (62)/5
Subject ID: US3672312; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-24							
Yes/ 2021-01-18 (146)/5	Yes/ 2021-01-18 (146)/5	No	No	Yes/ 2021-01-18 (146)/5	Yes/ 2021-01-18 (146)/5	No	No
Subject ID: US3672368; Age (Year): 23; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-28							
Yes/ 2021-01-18 (144)/5	Yes/ 2021-01-18 (144)/5	No	No	Yes/ 2021-01-18 (144)/5	Yes/ 2021-01-18 (144)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3682015; Age (Year): 36; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-22							
Yes/ 2020-12-22 (119)/5	Yes/ 2020-12-22 (119)/5	No	No	Yes/ 2020-12-22 (119)/5	Yes/ 2020-12-22 (119)/5	No	No
Subject ID: US3682018; Age (Year): 40; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-12-11 (108)/5	Yes/ 2020-12-11 (108)/5	Yes/ 2020-12-16 (113)/5	Yes/ 2020-12-16 (113)/5	Yes/ 2020-12-11 (108)/5	Yes/ 2020-12-11 (108)/5	No	No
Subject ID: US3682040; Age (Year): 48; Sex: M; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/							
Yes/ 2020-12-28 (119)/3	Yes/ 2020-12-28 (119)/3	No	No	Yes/ 2020-12-28 (119)/3	Yes/ 2020-12-28 (119)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3682180; Age (Year): 69; Sex: F; Race: MULTIPLE: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-02/2020-10-30							
No	No	No	No	Yes/ 2020-12-23 (83)/5	Yes/ 2020-12-23 (83)/5	No	No
Subject ID: US3682197; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-10							
Yes/ 2020-12-10 (59)/5	Yes/ 2020-12-10 (59)/5	No	No	Yes/ 2020-12-10 (59)/5	Yes/ 2020-12-10 (59)/5	No	No
Subject ID: US3692029; Age (Year): 27; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	No	No	No	Yes/ 2020-12-16 (107)/5	Yes/ 2020-12-16 (107)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3692096; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 21.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-08							
Yes/ 2020-12-10 (91)/5	Yes/ 2020-12-10 (91)/5	No	No	Yes/ 2020-12-10 (91)/5	Yes/ 2020-12-10 (91)/5	No	No
Subject ID: US3692149; Age (Year): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 25.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/							
No	No	No	No	Yes/ 2020-10-21 (28)/3	No	No	Yes/ 2020-10-21 (28)/3
Subject ID: US3692171; Age (Year): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 43.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-05/2020-11-06							
Yes/ 2021-01-08 (96)/5	Yes/ 2021-01-08 (96)/5	No	No	Yes/ 2021-01-08 (96)/5	Yes/ 2021-01-08 (96)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3702051; Age (Year): 43; Sex: F; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 43.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-02/2020-11-02							
Yes/ 2021-01-06 (97)/5	Yes/ 2021-01-06 (97)/5	Yes/ 2021-01-11 (102)/5	Yes/ 2021-01-11 (102)/5	Yes/ 2021-01-06 (97)/5	Yes/ 2021-01-06 (97)/5	No	No
Subject ID: US3712025; Age (Year): 74; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-07							
Yes/ 2021-01-05 (118)/5	Yes/ 2021-01-05 (118)/5	No	No	Yes/ 2021-01-05 (118)/5	Yes/ 2021-01-05 (118)/5	No	No
Subject ID: US3712059; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-28/2020-10-28							
Yes/ 2021-01-05 (100)/5	Yes/ 2021-01-05 (100)/5	No	No	Yes/ 2021-01-05 (100)/5	Yes/ 2021-01-05 (100)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3712096; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 52.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-15							
Yes/ 2020-12-07 (82)/5	Yes/ 2020-12-07 (82)/5	No	Yes/ 2020-12-08 (83)/5	Yes/ 2020-12-07 (82)/5	Yes/ 2020-12-07 (82)/5	No	No
Subject ID: US3712117; Age (Year): 73; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-21							
No	No	No	No	Yes/ 2020-10-21 (29)/4	No	No	Yes/ 2020-10-21 (29)/4
Subject ID: US3712129; Age (Year): 26; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-22							
Yes/ 2021-01-05 (104)/5	Yes/ 2021-01-05 (104)/5	No	No	Yes/ 2021-01-05 (104)/5	Yes/ 2021-01-05 (104)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3712142; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-21							
Yes/ 2021-01-21 (121)/5	Yes/ 2021-01-21 (121)/5	No	No	Yes/ 2021-01-21 (121)/5	Yes/ 2021-01-21 (121)/5	No	No
Subject ID: US3712150; Age (Year): 61; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 42.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-22							
Yes/ 2021-01-07 (106)/5	Yes/ 2021-01-07 (106)/5	No	No	Yes/ 2021-01-07 (106)/5	Yes/ 2021-01-07 (106)/5	No	No
Subject ID: US3712159; Age (Year): 35; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-20							
Yes/ 2020-10-20 (29)/4	Yes/ 2020-10-20 (29)/4	No	No	Yes/ 2020-10-20 (29)/4	Yes/ 2020-10-20 (29)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3712247; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-20							
Yes/ 2020-12-16 (55)/5	Yes/ 2020-12-16 (55)/5	No	No	Yes/ 2020-12-16 (55)/5	Yes/ 2020-12-16 (55)/5	No	No
Subject ID: US3712271; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-19							
Yes/ 2020-12-14 (54)/5	Yes/ 2020-12-14 (54)/5	Yes/ 2020-12-19 (59)/5	Yes/ 2020-12-19 (59)/5	Yes/ 2020-12-14 (54)/5	Yes/ 2020-12-14 (54)/5	No	No
Subject ID: US3712304; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-20							
Yes/ 2021-01-15 (85)/5	Yes/ 2021-01-15 (85)/5	No	No	Yes/ 2021-01-15 (85)/5	Yes/ 2021-01-15 (85)/5	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3712308; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-23							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2021-01-07	2021-01-07	2021-01-15	2021-01-15	2021-01-07	2021-01-07		
(77)/5	(77)/5	(85)/5	(85)/5	(77)/5	(77)/5		
Subject ID: US3722006; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): ; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-31							
Yes/	No	No	No	Yes/	Yes/	No	No
2020-11-16				2020-11-16	2020-11-16		
(109)/5				(109)/5	(109)/5		
Subject ID: US3722046; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-12-23	2020-12-23			2020-12-23	2020-12-23		
(143)/5	(143)/5			(143)/5	(143)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3722066; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-28							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2020-11-16	2020-11-16	2020-11-16	2020-11-16	2020-11-16	2020-11-16		
(106)/5	(106)/5	(106)/5	(106)/5	(106)/5	(106)/5		
Subject ID: US3722075; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-08-29							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2021-01-06	2021-01-06			2021-01-06	2021-01-06		
(156)/5	(156)/5			(156)/5	(156)/5		
Subject ID: US3722085; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-12-28	2020-12-28			2020-12-28	2020-12-28		
(147)/5	(147)/5			(147)/5	(147)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722095; Age (Year): 61; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-12-03 (121)/5	Yes/ 2020-12-03 (121)/5	No	No	Yes/ 2020-12-03 (121)/5	Yes/ 2020-12-03 (121)/5	No	No
Subject ID: US3722099; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-01							
Yes/ 2021-01-04 (153)/5	Yes/ 2021-01-04 (153)/5	No	No	Yes/ 2021-01-04 (153)/5	Yes/ 2021-01-04 (153)/5	No	No
Subject ID: US3722107; Age (Year): 61; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-12-03 (121)/5	Yes/ 2020-12-03 (121)/5	No	No	Yes/ 2020-12-03 (121)/5	Yes/ 2020-12-03 (121)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722121; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-08							
Yes/ 2020-12-30 (147)/5	Yes/ 2020-12-30 (147)/5	No	No	Yes/ 2020-12-30 (147)/5	Yes/ 2020-12-30 (147)/5	No	No
Subject ID: US3722124; Age (Year): 19; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (35)/4	No	No	Yes/ 2020-09-09 (35)/4
Subject ID: US3722150; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-18 (134)/5	Yes/ 2020-12-17 (133)/5	No	No	Yes/ 2020-12-17 (133)/5	Yes/ 2020-12-17 (133)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722154; Age (Year): 41; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-08							
Yes/ 2020-12-10 (126)/5	Yes/ 2020-12-10 (126)/5	No	No	Yes/ 2020-12-10 (126)/5	Yes/ 2020-12-10 (126)/5	No	No
Subject ID: US3722196; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-04							
Yes/ 2021-01-05 (148)/5	Yes/ 2021-01-05 (148)/5	No	No	Yes/ 2021-01-05 (148)/5	Yes/ 2021-01-05 (148)/5	No	No
Subject ID: US3722202; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-15							
No	No	No	No	Yes/ 2021-01-13 (155)/5	Yes/ 2021-01-13 (155)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722211; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-14							
Yes/ 2020-12-30 (141)/5	Yes/ 2020-12-30 (141)/5	No	No	Yes/ 2020-12-30 (141)/5	Yes/ 2020-12-30 (141)/5	No	No
Subject ID: US3722213; Age (Year): 34; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-16							
Yes/ 2021-01-05 (147)/5	Yes/ 2021-01-05 (147)/5	No	No	Yes/ 2021-01-05 (147)/5	Yes/ 2021-01-05 (147)/5	No	No
Subject ID: US3722228; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-09							
Yes/ 2021-01-04 (145)/5	Yes/ 2021-01-04 (145)/5	No	No	Yes/ 2021-01-04 (145)/5	Yes/ 2021-01-04 (145)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722255; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-12							
Yes/ 2021-01-05 (145)/5	Yes/ 2021-01-05 (145)/5	No	No	Yes/ 2021-01-05 (145)/5	Yes/ 2021-01-05 (145)/5	No	No
Subject ID: US3722275; Age (Year): 45; Sex: M; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 48.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-12							
Yes/ 2020-12-07 (115)/5	Yes/ 2020-12-07 (115)/5	No	No	Yes/ 2020-12-07 (115)/5	Yes/ 2020-12-07 (115)/5	No	No
Subject ID: US3722316; Age (Year): 25; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2021-01-11 (146)/5	Yes/ 2021-01-11 (146)/5	No	No	Yes/ 2021-01-11 (146)/5	Yes/ 2021-01-11 (146)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722322; Age (Year): 46; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/							
Yes/ 2020-12-07 (104)/3	Yes/ 2020-12-07 (104)/3	No	No	Yes/ 2020-12-07 (104)/3	Yes/ 2020-12-07 (104)/3	No	No
Subject ID: US3722347; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-12-29 (131)/5	Yes/ 2020-12-29 (131)/5	No	No	Yes/ 2020-12-29 (131)/5	Yes/ 2020-12-29 (131)/5	No	No
Subject ID: US3722375; Age (Year): 28; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-23							
Yes/ 2020-11-09 (77)/5	Yes/ 2020-11-09 (77)/5	No	No	Yes/ 2020-11-09 (77)/5	Yes/ 2020-11-09 (77)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3722382; Age (Year): 73; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-10-15 (52)/5	Yes/ 2020-10-20 (57)/5	No	No	Yes/ 2020-10-20 (57)/5	Yes/ 2020-10-20 (57)/5	No	No
Subject ID: US3722419; Age (Year): 69; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-16							
No	Yes/ 2020-10-24 (41)/4	No	No	Yes/ 2020-10-16 (33)/4	Yes/ 2020-10-24 (41)/4	No	Yes/ 2020-10-16 (33)/4
Subject ID: US3722431; Age (Year): 35; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 47.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-01/2020-10-30							
Yes/ 2021-01-05 (97)/5	Yes/ 2021-01-05 (97)/5	No	No	Yes/ 2021-01-05 (97)/5	Yes/ 2021-01-05 (97)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3732207; Age (Year): 30; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/							
Yes/ 2020-09-18 (23)/3	Yes/ 2020-09-18 (23)/3	No	No	Yes/ 2020-09-18 (23)/3	Yes/ 2020-09-18 (23)/3	No	No
Subject ID: US3732235; Age (Year): 86; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2021-01-06 (129)/5	Yes/ 2021-01-06 (129)/5	No	Yes/ 2021-01-20 (143)/5	Yes/ 2021-01-06 (129)/5	Yes/ 2021-01-06 (129)/5	No	No
Subject ID: US3732280; Age (Year): 32; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-06							
Yes/ 2020-12-21 (109)/5	Yes/ 2020-12-21 (109)/5	No	No	Yes/ 2020-12-21 (109)/5	Yes/ 2020-12-21 (109)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3732306; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
No	No	No	No	Yes/ 2020-10-28 (50)/5	Yes/ 2020-10-28 (50)/5	No	No
Subject ID: US3732361; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-16							
No	No	No	No	Yes/ 2020-10-16 (29)/4	No	No	Yes/ 2020-10-16 (29)/4
Subject ID: US3732371; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-21							
Yes/ 2020-12-31 (100)/5	Yes/ 2020-12-31 (100)/5	No	No	Yes/ 2020-12-31 (100)/5	Yes/ 2020-12-31 (100)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3732401; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 40.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-20							
Yes/ 2020-12-28 (69)/5	Yes/ 2020-12-28 (69)/5	No	No	Yes/ 2020-12-28 (69)/5	Yes/ 2020-12-28 (69)/5	No	No
Subject ID: US3742022; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-12-02 (106)/5	Yes/ 2020-12-02 (106)/5	No	No	Yes/ 2020-12-02 (106)/5	Yes/ 2020-12-02 (106)/5	No	No
Subject ID: US3742041; Age (Year): 30; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-18							
Yes/ 2020-12-10 (111)/5	Yes/ 2020-12-10 (111)/5	No	No	Yes/ 2020-12-10 (111)/5	Yes/ 2020-12-10 (111)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3742047; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-19							
Yes/ 2021-01-13 (145)/5	Yes/ 2021-01-13 (145)/5	No	No	Yes/ 2021-01-13 (145)/5	Yes/ 2021-01-13 (145)/5	No	No
Subject ID: US3742120; Age (Year): 44; Sex: F; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2020-12-28 (120)/5	Yes/ 2020-12-28 (120)/5	No	No	Yes/ 2020-12-28 (120)/5	Yes/ 2020-12-28 (120)/5	No	No
Subject ID: US3742123; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-08							
Yes/ 2020-10-21 (49)/4	Yes/ 2020-10-21 (49)/4	Yes/ 2020-10-27 (55)/5	Yes/ 2020-10-27 (55)/5	Yes/ 2020-10-21 (49)/4	Yes/ 2020-10-21 (49)/4	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3742160; Age (Year): 87; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-29/2020-09-26							
Yes/ 2020-11-24 (88)/5	Yes/ 2020-11-24 (88)/5	No	No	Yes/ 2020-11-24 (88)/5	Yes/ 2020-11-24 (88)/5	No	No
Subject ID: US3742247; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-01							
No	No	No	No	Yes/ 2020-12-16 (104)/5	Yes/ 2020-12-16 (104)/5	No	No
Subject ID: US3742253; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/							
Yes/ 2020-09-25 (22)/3	Yes/ 2020-09-25 (22)/3	No	No	Yes/ 2020-09-25 (22)/3	Yes/ 2020-09-25 (22)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3742273; Age (Year): 45; Sex: M; Race: OTHER: HISPANIC; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 35.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-05/2020-10-03							
Yes/ 2020-12-28 (115)/5	Yes/ 2020-12-28 (115)/5	No	No	Yes/ 2020-12-28 (115)/5	Yes/ 2020-12-28 (115)/5	No	No
Subject ID: US3742293; Age (Year): 42; Sex: M; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 35.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/							
Yes/ 2021-01-11 (125)/3	Yes/ 2021-01-11 (125)/3	No	No	Yes/ 2021-01-11 (125)/3	Yes/ 2021-01-11 (125)/3	No	No
Subject ID: US3742408; Age (Year): 53; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-22							
Yes/ 2020-12-07 (75)/5	Yes/ 2020-12-07 (75)/5	No	No	Yes/ 2020-12-07 (75)/5	Yes/ 2020-12-07 (75)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3742477; Age (Year): 49; Sex: F; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 43.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-01/							
Yes/ 2020-10-19 (19)/3	Yes/ 2020-10-19 (19)/3	No	No	Yes/ 2020-10-19 (19)/3	Yes/ 2020-10-19 (19)/3	No	No
Subject ID: US3742491; Age (Year): 20; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-05							
Yes/ 2020-12-22 (76)/5	Yes/ 2020-12-22 (76)/5	No	No	Yes/ 2020-12-22 (76)/5	Yes/ 2020-12-22 (76)/5	No	No
Subject ID: US3752025; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-21							
Yes/ 2020-11-11 (94)/5	Yes/ 2020-11-11 (94)/5	Yes/ 2020-11-11 (94)/5	Yes/ 2020-11-11 (94)/5	Yes/ 2020-11-10 (93)/5	Yes/ 2020-11-10 (93)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3752069; Age (Year): 31; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 59.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-10							
Yes/ 2020-10-31 (80)/5	Yes/ 2020-11-04 (84)/5	No	No	Yes/ 2020-11-04 (84)/5	Yes/ 2020-11-04 (84)/5	No	No
Subject ID: US3752161; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-10-27 (70)/5	Yes/ 2020-10-27 (70)/5	No	No	Yes/ 2020-10-27 (70)/5	Yes/ 2020-10-27 (70)/5	No	No
Subject ID: US3752162; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-10-17 (60)/5	Yes/ 2020-10-27 (70)/5	Yes/ 2020-10-18 (61)/5	Yes/ 2020-10-27 (70)/5	Yes/ 2020-10-27 (70)/5	Yes/ 2020-10-27 (70)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3752208; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-11-24 (96)/5	Yes/ 2020-11-24 (96)/5	No	No	Yes/ 2020-11-24 (96)/5	Yes/ 2020-11-24 (96)/5	No	No
Subject ID: US3752213; Age (Year): 46; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
Yes/ 2020-12-28 (130)/5	Yes/ 2020-12-28 (130)/5	No	No	Yes/ 2020-12-28 (130)/5	Yes/ 2020-12-28 (130)/5	No	No
Subject ID: US3752225; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-24							
Yes/ 2021-01-04 (134)/5	Yes/ 2021-01-04 (134)/5	No	No	Yes/ 2021-01-04 (134)/5	Yes/ 2021-01-04 (134)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3752229; Age (Year): 45; Sex: F; Race: OTHER; LATINO; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-10-27 (65)/5	Yes/ 2020-10-27 (65)/5	Yes/ 2020-11-02 (71)/5	Yes/ 2020-11-02 (71)/5	Yes/ 2020-10-27 (65)/5	Yes/ 2020-10-27 (65)/5	No	No
Subject ID: US3752250; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-09 (77)/5	Yes/ 2020-11-09 (77)/5	No	No	Yes/ 2020-11-09 (77)/5	Yes/ 2020-11-09 (77)/5	No	No
Subject ID: US3752319; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-25							
Yes/ 2020-12-15 (107)/5	Yes/ 2020-12-15 (107)/5	No	No	Yes/ 2020-12-15 (107)/5	Yes/ 2020-12-15 (107)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3752344; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-10-01							
Yes/ 2020-10-20 (50)/5	Yes/ 2020-10-20 (50)/5	No	No	Yes/ 2020-10-20 (50)/5	Yes/ 2020-10-20 (50)/5	No	No
Subject ID: US3752347; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-28							
Yes/ 2020-10-13 (43)/5	Yes/ 2020-10-13 (43)/5	No	No	Yes/ 2020-10-13 (43)/5	Yes/ 2020-10-13 (43)/5	No	No
Subject ID: US3752366; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/							
Yes/ 2020-09-08 (7)/2	Yes/ 2020-09-08 (7)/2	No	No	Yes/ 2020-09-08 (7)/2	Yes/ 2020-09-08 (7)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Note: Footnotes are listed on the last page.

Program Path: \\wilbta\wilbta01\Moderna MODMRNA1273P301 U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3762251; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-08							
No	Yes/ 2020-12-31 (112)/5	No	Yes/ 2021-01-05 (117)/5	Yes/ 2020-12-31 (112)/5	Yes/ 2020-12-31 (112)/5	No	No
Subject ID: US3772004; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-08-31							
Yes/ 2020-11-10 (99)/5	Yes/ 2020-11-10 (99)/5	No	Yes/ 2020-11-11 (100)/5	Yes/ 2020-11-10 (99)/5	Yes/ 2020-11-10 (99)/5	No	No
Subject ID: US3772026; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-10							
Yes/ 2020-12-14 (131)/5	Yes/ 2020-12-14 (131)/5	No	No	Yes/ 2020-12-14 (131)/5	Yes/ 2020-12-14 (131)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3772035; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-14							
Yes/ 2020-11-16 (99)/5	Yes/ 2020-11-16 (99)/5	Yes/ 2020-11-18 (101)/5	No	Yes/ 2020-11-16 (99)/5	Yes/ 2020-11-16 (99)/5	No	No
Subject ID: US3772047; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-11-24 (106)/5	Yes/ 2020-11-24 (106)/5	No	No	Yes/ 2020-11-24 (106)/5	Yes/ 2020-11-24 (106)/5	No	No
Subject ID: US3772095; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-14							
Yes/ 2020-12-09 (113)/5	Yes/ 2020-12-09 (113)/5	No	No	Yes/ 2020-12-09 (113)/5	Yes/ 2020-12-09 (113)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3772106; Age (Year): 47; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-18							
Yes/ 2021-01-06 (140)/5	Yes/ 2021-01-06 (140)/5	No	No	Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-06 (140)/5	No	No
Subject ID: US3772149; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-22							
No	No	No	No	Yes/ 2020-09-22 (30)/4	No	No	Yes/ 2020-09-22 (30)/4
Subject ID: US3772153; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 50.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-10-15							
No	No	No	No	Yes/ 2021-01-22 (149)/5	Yes/ 2021-01-22 (149)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]								
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*		COVID-19*		Severe COVID-19*				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*					
Subject ID: US3772159; Age (Year): 76; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-25								
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No	
2020-12-03	2020-12-03	2020-12-08	2020-12-08	2020-12-03	2020-12-03			
(99)/5	(99)/5	(104)/5	(104)/5	(99)/5	(99)/5			
Subject ID: US3772162; Age (Year): 75; Sex: M; Race: MULTIPLE; (b) (6)								
(b) (6)	Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-25							
Yes/	Yes/	No	No	Yes/	Yes/	No	No	
2020-12-04	2020-12-04			2020-12-04	2020-12-04			
(100)/5	(100)/5			(100)/5	(100)/5			
Subject ID: US3772166; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25								
No	No	No	No	Yes/	No	No	Yes/	
				2020-09-25			2020-09-25	
				(29)/4			(29)/4	

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3772182; Age (Year): 51; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-30							
Yes/ 2020-11-16 (78)/5	Yes/ 2020-11-16 (78)/5	No	No	Yes/ 2020-11-16 (78)/5	Yes/ 2020-11-16 (78)/5	No	No
Subject ID: US3772184; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-30							
Yes/ 2020-11-20 (82)/5	Yes/ 2020-11-20 (82)/5	No	No	Yes/ 2020-11-20 (82)/5	Yes/ 2020-11-20 (82)/5	No	No
Subject ID: US3772208; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-14							
No	Yes/ 2020-10-06 (34)/3	No	No	Yes/ 2020-10-06 (34)/3	Yes/ 2020-10-06 (34)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3772246; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-09							
Yes/ 2020-11-13 (65)/5	Yes/ 2020-11-13 (65)/5	No	No	Yes/ 2020-11-13 (65)/5	Yes/ 2020-11-13 (65)/5	No	No
Subject ID: US3772251; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 49.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-13							
Yes/ 2021-01-25 (137)/5	Yes/ 2021-01-25 (137)/5	No	No	Yes/ 2021-01-25 (137)/5	Yes/ 2021-01-25 (137)/5	No	No
Subject ID: US3782016; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-10-11 (59)/5	Yes/ 2020-10-11 (59)/5	No	No	Yes/ 2020-10-11 (59)/5	Yes/ 2020-10-11 (59)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3782033; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
Yes/ 2020-10-30 (75)/5	Yes/ 2020-10-30 (75)/5	No	No	Yes/ 2020-10-30 (75)/5	Yes/ 2020-10-30 (75)/5	No	No
Subject ID: US3782050; Age (Year): 30; Sex: M; Race: MULTIPLE: (b) (6); Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-10-19 (62)/5	Yes/ 2020-10-19 (62)/5	No	No	Yes/ 2020-10-19 (62)/5	Yes/ 2020-10-19 (62)/5	No	No
Subject ID: US3782053; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-21							
Yes/ 2020-11-28 (102)/5	Yes/ 2020-11-28 (102)/5	No	No	Yes/ 2020-11-28 (102)/5	Yes/ 2020-11-28 (102)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3782071; Age (Year): 65; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-21							
Yes/ 2020-11-27 (99)/5	Yes/ 2020-11-27 (99)/5	No	No	Yes/ 2020-11-27 (99)/5	Yes/ 2020-11-27 (99)/5	No	No
Subject ID: US3782082; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 55.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-11-04 (72)/5	Yes/ 2020-11-04 (72)/5	No	Yes/ 2020-11-04 (72)/5	Yes/ 2020-11-04 (72)/5	Yes/ 2020-11-04 (72)/5	No	No
Subject ID: US3782136; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-30							
Yes/ 2020-11-11 (71)/5	Yes/ 2020-11-11 (71)/5	No	No	Yes/ 2020-11-10 (70)/5	Yes/ 2020-11-10 (70)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3782168; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-13							
Yes/ 2020-11-12 (63)/5	Yes/ 2020-11-12 (63)/5	No	No	Yes/ 2020-11-11 (62)/5	Yes/ 2020-11-11 (62)/5	No	No
Subject ID: US3792005; Age (Year): 55; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 31.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
No	No	No	No	Yes/ 2020-09-04 (29)/4	No	No	Yes/ 2020-09-04 (29)/4
Subject ID: US3792052; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-13							
Yes/ 2020-11-23 (70)/5	Yes/ 2020-11-23 (70)/5	No	No	Yes/ 2020-11-23 (70)/5	Yes/ 2020-11-23 (70)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3792080; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/2020-11-04							
Yes/ 2020-12-05 (67)/5	Yes/ 2020-12-05 (67)/5	No	No	Yes/ 2020-12-05 (67)/5	Yes/ 2020-12-05 (67)/5	No	No
Subject ID: US3792090; Age (Year): 24; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-05							
Yes/ 2020-12-14 (69)/5	Yes/ 2020-12-14 (69)/5	No	No	Yes/ 2020-12-14 (69)/5	Yes/ 2020-12-14 (69)/5	No	No
Subject ID: US3802034; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-21							
Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-13 (81)/5	Yes/ 2020-11-13 (81)/5	Yes/ 2020-11-05 (73)/5	Yes/ 2020-11-05 (73)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3802046; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-11-13 (80)/5	Yes/ 2020-11-13 (80)/5	Yes/ 2020-11-24 (91)/5	Yes/ 2020-11-24 (91)/5	Yes/ 2020-11-13 (80)/5	Yes/ 2020-11-13 (80)/5	No	No
Subject ID: US3802091; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-11-03 (64)/5	Yes/ 2020-11-03 (64)/5	No	No	Yes/ 2020-11-03 (64)/5	Yes/ 2020-11-03 (64)/5	No	No
Subject ID: US3802109; Age (Year): 22; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 52.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-10-02							
Yes/ 2021-01-11 (132)/5	Yes/ 2021-01-11 (132)/5	Yes/ 2021-01-17 (138)/5	Yes/ 2021-01-17 (138)/5	Yes/ 2021-01-11 (132)/5	Yes/ 2021-01-11 (132)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3802149; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-07/2020-10-08							
Yes/ 2020-11-23 (78)/5	Yes/ 2020-11-23 (78)/5	No	No	Yes/ 2020-11-23 (78)/5	Yes/ 2020-11-23 (78)/5	No	No
Subject ID: US3802185; Age (Year): 52; Sex: F; Race: MULTIPLE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-12							
Yes/ 2020-11-14 (67)/5	Yes/ 2020-11-14 (67)/5	Yes/ 2020-11-14 (67)/5	Yes/ 2020-11-14 (67)/5	Yes/ 2020-11-11 (64)/5	Yes/ 2020-11-11 (64)/5	No	No
Subject ID: US3802220; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-13							
Yes/ 2020-12-21 (102)/5	Yes/ 2020-12-21 (102)/5	No	No	Yes/ 2020-12-21 (102)/5	Yes/ 2020-12-21 (102)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3812044; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-08-31							
Yes/ 2020-09-28 (55)/5	Yes/ 2020-09-28 (55)/5	No	No	Yes/ 2020-09-28 (55)/5	Yes/ 2020-09-28 (55)/5	No	No
Subject ID: US3812046; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-08-31							
Yes/ 2020-12-07 (125)/5	Yes/ 2020-12-07 (125)/5	No	No	Yes/ 2020-12-07 (125)/5	Yes/ 2020-12-07 (125)/5	No	No
Subject ID: US3812111; Age (Year): 51; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-04							
Yes/ 2020-12-14 (127)/5	Yes/ 2020-12-14 (127)/5	No	No	Yes/ 2020-12-14 (127)/5	Yes/ 2020-12-14 (127)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3812114; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-08							
Yes/ 2020-12-02 (115)/5	Yes/ 2020-11-30 (113)/5	No	No	Yes/ 2020-11-30 (113)/5	Yes/ 2020-11-30 (113)/5	No	No
Subject ID: US3812137; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-11							
Yes/ 2020-12-02 (113)/5	Yes/ 2020-12-02 (113)/5	No	No	Yes/ 2020-12-02 (113)/5	Yes/ 2020-12-02 (113)/5	No	No
Subject ID: US3812139; Age (Year): 69; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-10							
Yes/ 2020-11-23 (104)/5	Yes/ 2020-11-23 (104)/5	No	No	Yes/ 2020-11-23 (104)/5	Yes/ 2020-11-23 (104)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3812153; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-15							
Yes/ 2020-12-23 (133)/5	Yes/ 2020-12-23 (133)/5	No	No	Yes/ 2020-12-23 (133)/5	Yes/ 2020-12-23 (133)/5	No	No
Subject ID: US3812168; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-18							
Yes/ 2020-11-06 (85)/5	Yes/ 2020-11-06 (85)/5	No	No	Yes/ 2020-11-06 (85)/5	Yes/ 2020-11-06 (85)/5	No	No
Subject ID: US3812174; Age (Year): 18; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
Yes/ 2020-09-10 (28)/3	Yes/ 2020-09-10 (28)/3	No	No	Yes/ 2020-09-10 (28)/3	Yes/ 2020-09-10 (28)/3	No	No

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3812175; Age (Year): 25; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 55.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-10							
Yes/ 2020-11-23 (102)/5	Yes/ 2020-11-23 (102)/5	No	No	Yes/ 2020-11-23 (102)/5	Yes/ 2020-11-23 (102)/5	No	No
Subject ID: US3812197; Age (Year): 38; Sex: M; Race: MULTIPLE: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/							
Yes/ 2020-08-27 (11)/2	Yes/ 2020-08-27 (11)/2	No	No	Yes/ 2020-08-27 (11)/2	Yes/ 2020-08-27 (11)/2	No	No
Subject ID: US3812216; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-17							
Yes/ 2020-10-11 (54)/5	Yes/ 2020-10-13 (56)/5	No	No	Yes/ 2020-10-13 (56)/5	Yes/ 2020-10-13 (56)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3812224; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): ; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-14							
Yes/ 2021-01-11 (145)/5	Yes/ 2021-01-11 (145)/5	No	No	Yes/ 2021-01-11 (145)/5	Yes/ 2021-01-11 (145)/5	No	No
Subject ID: US3812270; Age (Year): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-24							
Yes/ 2020-12-02 (99)/5	Yes/ 2020-12-02 (99)/5	No	No	Yes/ 2020-12-02 (99)/5	Yes/ 2020-12-02 (99)/5	No	No
Subject ID: US3812272; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-24							
Yes/ 2020-11-13 (80)/5	Yes/ 2020-11-13 (80)/5	No	No	Yes/ 2020-11-13 (80)/5	Yes/ 2020-11-13 (80)/5	No	No

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301 U\BLA\TLF\l1602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Secondary Definition	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3812280; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/	No	No	No	No	No	No	No
2020-11-19							
(85)/5							
Subject ID: US3812285; Age (Year): 63; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-24							
No	No	No	No	Yes/	Yes/	No	No
				2020-12-22	2020-12-22		
				(117)/5	(117)/5		
Subject ID: US3812323; Age (Year): 28; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-16							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-11-02	2020-11-02			2020-11-02	2020-11-02		
(53)/5	(53)/5			(53)/5	(53)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic SARS-CoV-2 Infection	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	
Subject ID: US3812346; Age (Year): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-02/2020-10-29							
No	No	No	No	Yes/ 2020-10-29 (28)/4	No	No	Yes/ 2020-10-29 (28)/4
Subject ID: US3822048; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-10-20 (75)/5	Yes/ 2020-10-20 (75)/5	No	No	Yes/ 2020-10-20 (75)/5	Yes/ 2020-10-20 (75)/5	No	No
Subject ID: US3822143; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 21.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
No	No	No	No	Yes/ 2020-11-19 (98)/5	Yes/ 2020-11-19 (98)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		COVID-19*		Definition of COVID-19*		Death Caused by COVID-19	
Subject ID: US3822162; Age (Year): 25; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-23							
No	No	No	No	Yes/ 2020-12-28 (133)/5	Yes/ 2020-12-28 (133)/5	No	No
Subject ID: US3822180; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-16							
Yes/ 2020-11-13 (88)/5	Yes/ 2020-11-13 (88)/5	No	No	Yes/ 2020-11-05 (80)/5	Yes/ 2020-11-05 (80)/5	No	No
Subject ID: US3822200; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-24							
Yes/ 2020-10-09 (51)/5	Yes/ 2020-10-09 (51)/5	No	No	Yes/ 2020-10-09 (51)/5	Yes/ 2020-10-09 (51)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3822244; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-25							
Yes/ 2020-11-23 (92)/5	No	No	No	Yes/ 2020-11-23 (92)/5	Yes/ 2020-11-23 (92)/5	No	No
Subject ID: US3822304; Age (Year): 62; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-10-01							
Yes/ 2020-12-14 (109)/5	Yes/ 2020-12-14 (109)/5	No	No	Yes/ 2020-12-14 (109)/5	Yes/ 2020-12-14 (109)/5	No	No
Subject ID: US3832011; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
No	Yes/ 2020-12-30 (153)/5	No	No	Yes/ 2020-12-30 (153)/5	Yes/ 2020-12-30 (153)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3832012; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-27							
Yes/ 2020-12-15 (138)/5	Yes/ 2020-12-15 (138)/5	No	No	Yes/ 2020-12-15 (138)/5	Yes/ 2020-12-15 (138)/5	No	No
Subject ID: US3832031; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-08-28							
No	No	No	No	Yes/ 2020-08-28 (28)/4	No	No	Yes/ 2020-08-28 (28)/4
Subject ID: US3832052; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-09-01							
Yes/ 2020-12-17 (137)/5	Yes/ 2020-12-17 (137)/5	No	No	Yes/ 2020-12-17 (137)/5	Yes/ 2020-12-17 (137)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3832059; Age (Year): 22; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-29							
Yes/ 2021-01-07 (158)/5	Yes/ 2021-01-07 (158)/5	No	No	Yes/ 2021-01-07 (158)/5	Yes/ 2021-01-07 (158)/5	No	No
Subject ID: US3832118; Age (Year): 71; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-09-22 (48)/5	Yes/ 2020-09-22 (48)/5	No	No	Yes/ 2020-09-22 (48)/5	Yes/ 2020-09-22 (48)/5	No	No
Subject ID: US3832121; Age (Year): 72; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-10-22 (78)/5	Yes/ 2020-10-22 (78)/5	No	No	Yes/ 2020-10-22 (78)/5	Yes/ 2020-10-22 (78)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3832151; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
No	Yes/ 2020-12-28 (140)/5	No	No	Yes/ 2020-12-28 (140)/5	Yes/ 2020-12-28 (140)/5	No	No
Subject ID: US3832155; Age (Year): 29; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2020-12-16 (128)/5	Yes/ 2020-12-16 (128)/5	No	No	Yes/ 2020-12-16 (128)/5	Yes/ 2020-12-16 (128)/5	No	No
Subject ID: US3832199; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
No	No	No	No	Yes/ 2020-09-14 (29)/4	No	No	Yes/ 2020-09-14 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3832214; Age (Year): 65; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
No	No	No	No	Yes/ 2020-09-15 (29)/4	No	No	Yes/ 2020-09-15 (29)/4
Subject ID: US3842039; Age (Year): 51; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-23							
Yes/ 2020-12-17 (91)/5	Yes/ 2020-12-17 (91)/5	No	No	Yes/ 2020-12-16 (90)/5	Yes/ 2020-12-16 (90)/5	No	No
Subject ID: US3842040; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-16							
Yes/ 2020-11-03 (47)/5	Yes/ 2020-11-03 (47)/5	Yes/ 2020-11-08 (52)/5	Yes/ 2020-11-08 (52)/5	Yes/ 2020-11-03 (47)/5	Yes/ 2020-11-03 (47)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3842057; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-09/2020-11-10							
Yes/ 2020-12-23 (76)/5	Yes/ 2020-12-23 (76)/5	No	No	Yes/ 2020-12-23 (76)/5	Yes/ 2020-12-23 (76)/5	No	No
Subject ID: US3852015; Age (Year): 69; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-12-19 (118)/5	Yes/ 2020-12-19 (118)/5	No	No	Yes/ 2020-12-18 (117)/5	Yes/ 2020-12-18 (117)/5	No	No
Subject ID: US3852019; Age (Year): 47; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-24							
Yes/ 2020-12-15 (113)/5	Yes/ 2020-12-15 (113)/5	No	No	Yes/ 2020-12-15 (113)/5	Yes/ 2020-12-15 (113)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3852045; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-10-18 (53)/5	Yes/ 2020-10-18 (53)/5	No	No	Yes/ 2020-10-16 (51)/5	Yes/ 2020-10-16 (51)/5	No	No
Subject ID: US3852064; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-25							
Yes/ 2020-11-28 (93)/5	Yes/ 2020-12-02 (97)/5	No	No	Yes/ 2020-12-02 (97)/5	Yes/ 2020-12-02 (97)/5	No	No
Subject ID: US3852070; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-25							
Yes/ 2020-10-12 (43)/5	Yes/ 2020-10-12 (43)/5	No	No	Yes/ 2020-10-12 (43)/5	Yes/ 2020-10-12 (43)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3852086; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT REPORTED; BMI (kg/m ²): 22.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-10-01							
Yes/ 2021-01-05 (126)/5	Yes/ 2021-01-05 (126)/5	No	No	Yes/ 2020-12-28 (118)/5	Yes/ 2020-12-28 (118)/5	No	No
Subject ID: US3852090; Age (Year): 37; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-28							
Yes/ 2020-11-05 (65)/5	Yes/ 2020-11-05 (65)/5	No	No	Yes/ 2020-11-05 (65)/5	Yes/ 2020-11-05 (65)/5	No	No
Subject ID: US3852114; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-06							
Yes/ 2021-01-22 (141)/5	Yes/ 2021-01-22 (141)/5	No	No	Yes/ 2021-01-22 (141)/5	Yes/ 2021-01-22 (141)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3852122; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 15.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-05							
Yes/ 2020-12-22 (106)/5	Yes/ 2020-12-22 (106)/5	Yes/ 2020-12-23 (107)/5	Yes/ 2020-12-22 (106)/5	Yes/ 2020-12-22 (106)/5	Yes/ 2020-12-22 (106)/5	No	No
Subject ID: US3852147; Age (Year): 73; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2020-11-09 (62)/5	Yes/ 2020-11-09 (62)/5	No	No	Yes/ 2020-11-09 (62)/5	Yes/ 2020-11-09 (62)/5	No	No
Subject ID: US3852178; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-09							
Yes/ 2020-11-09 (60)/5	Yes/ 2020-11-09 (60)/5	No	No	Yes/ 2020-11-09 (60)/5	Yes/ 2020-11-09 (60)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3852185; Age (Year): 32; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-16							
No	No	No	No	Yes/ 2020-12-28 (104)/5	Yes/ 2020-12-28 (104)/5	No	No
Subject ID: US3862050; Age (Year): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/							
Yes/ 2020-09-01 (9)/2	Yes/ 2020-09-01 (9)/2	No	No	Yes/ 2020-09-01 (9)/2	Yes/ 2020-09-01 (9)/2	No	No
Subject ID: US3862053; Age (Year): 74; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
Yes/ 2020-10-19 (57)/5	Yes/ 2020-10-19 (57)/5	No	No	Yes/ 2020-10-19 (57)/5	Yes/ 2020-10-19 (57)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3862157; Age (Year): 38; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2020-12-08 (91)/5	Yes/ 2020-12-08 (91)/5	No	No	Yes/ 2020-12-08 (91)/5	Yes/ 2020-12-08 (91)/5	No	No
Subject ID: US3862169; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-12							
Yes/ 2020-12-28 (109)/5	Yes/ 2020-12-28 (109)/5	No	No	Yes/ 2020-12-28 (109)/5	Yes/ 2020-12-28 (109)/5	No	No
Subject ID: US3862172; Age (Year): 32; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-12							
No	No	No	No	Yes/ 2020-10-12 (32)/4	No	No	Yes/ 2020-10-12 (32)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3862196; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-14							
Yes/ 2020-12-21 (97)/5	Yes/ 2020-12-21 (97)/5	No	No	Yes/ 2020-12-21 (97)/5	Yes/ 2020-12-21 (97)/5	No	No
Subject ID: US3872033; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-15							
Yes/ 2020-09-08 (36)/3	Yes/ 2020-09-08 (36)/3	No	No	Yes/ 2020-09-08 (36)/3	Yes/ 2020-09-08 (36)/3	No	No
Subject ID: US3872095; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	Yes/ 2020-12-23 (139)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3872101; Age (Year): 73; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-03 (119)/5	Yes/ 2020-12-03 (119)/5	No	No	Yes/ 2020-12-03 (119)/5	Yes/ 2020-12-03 (119)/5	No	No
Subject ID: US3872112; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-08							
Yes/ 2020-12-18 (131)/5	Yes/ 2020-12-18 (131)/5	No	No	Yes/ 2020-12-18 (131)/5	Yes/ 2020-12-18 (131)/5	No	No
Subject ID: US3872141; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
No	No	No	No	Yes/ 2020-10-08 (59)/5	No	No	Yes/ 2020-10-08 (59)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3872163; Age (Year): 53; Sex: F; Race: ASIAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-17							
No	No	No	No	Yes/ 2020-09-17 (36)/4	No	No	Yes/ 2020-09-17 (36)/4
Subject ID: US3872205; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-17							
Yes/ 2020-12-31 (137)/5	Yes/ 2020-12-31 (137)/5	No	No	Yes/ 2020-12-31 (137)/5	Yes/ 2020-12-31 (137)/5	No	No
Subject ID: US3872223; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 38.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
Yes/ 2020-09-21 (34)/4	Yes/ 2020-09-21 (34)/4	Yes/ 2020-10-18 (61)/5	No	Yes/ 2020-09-16 (29)/4	Yes/ 2020-09-21 (34)/4	No	Yes/ 2020-09-16 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3872253; Age (Year): 30; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 20.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-24							
No	No	No	No	Yes/ 2020-10-29 (70)/5	Yes/ 2020-10-29 (70)/5	No	No
Subject ID: US3872263; Age (Year): 19; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 32.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-28							
No	No	No	No	Yes/ 2020-11-04 (73)/5	Yes/ 2020-11-04 (73)/5	No	No
Subject ID: US3872295; Age (Year): 46; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-10-05							
Yes/ 2020-12-14 (112)/5	Yes/ 2020-12-14 (112)/5	No	No	Yes/ 2020-12-14 (112)/5	Yes/ 2020-12-14 (112)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3872315; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 36.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-10-01							
No	No	No	No	Yes/ 2020-10-28 (64)/5	No	No	Yes/ 2020-10-28 (64)/5
Subject ID: US3872317; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-12-08 (105)/5	Yes/ 2020-12-08 (105)/5	No	No	Yes/ 2020-12-08 (105)/5	Yes/ 2020-12-08 (105)/5	No	No
Subject ID: US3872377; Age (Year): 36; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-05							
Yes/ 2020-11-24 (86)/5	Yes/ 2020-11-24 (86)/5	Yes/ 2020-12-13 (105)/5	Yes/ 2020-12-13 (105)/5	Yes/ 2020-11-24 (86)/5	Yes/ 2020-11-24 (86)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3872384; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-14							
Yes/ 2020-12-08 (100)/5	Yes/ 2020-12-08 (100)/5	No	No	Yes/ 2020-12-08 (100)/5	Yes/ 2020-12-08 (100)/5	No	No
Subject ID: US3872482; Age (Year): 61; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/							
Yes/ 2020-12-21 (104)/3	Yes/ 2020-12-21 (104)/3	No	No	Yes/ 2020-12-21 (104)/3	Yes/ 2020-12-21 (104)/3	No	No
Subject ID: US3872483; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/							
Yes/ 2020-12-14 (97)/3	Yes/ 2020-12-14 (97)/3	No	No	Yes/ 2020-12-14 (97)/3	Yes/ 2020-12-14 (97)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3892059; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-05							
Yes/ 2020-11-30 (84)/5	Yes/ 2020-11-30 (84)/5	Yes/ 2020-12-02 (86)/5	Yes/ 2020-12-02 (86)/5	Yes/ 2020-11-30 (84)/5	Yes/ 2020-11-30 (84)/5	No	No
Subject ID: US3892072; Age (Year): 77; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-07							
No	No	No	No	Yes/ 2020-10-07 (28)/4	No	No	Yes/ 2020-10-07 (28)/4
Subject ID: US3902015; Age (Year): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
Yes/ 2020-10-28 (51)/5	Yes/ 2020-10-28 (51)/5	Yes/ 2020-11-06 (60)/5	Yes/ 2020-11-06 (60)/5	Yes/ 2020-10-28 (51)/5	Yes/ 2020-10-28 (51)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3902054; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-05							
No	No	No	No	Yes/ 2020-11-05 (58)/5	No	No	Yes/ 2020-11-05 (58)/5
Subject ID: US3902064; Age (Year): 50; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.4; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/							
Yes/ 2020-09-18 (9)/2	Yes/ 2020-09-18 (9)/2	No	No	Yes/ 2020-09-18 (9)/2	Yes/ 2020-09-18 (9)/2	No	No
Subject ID: US3902132; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-16/2020-11-13							
Yes/ 2020-12-04 (50)/5	Yes/ 2020-12-04 (50)/5	No	No	Yes/ 2020-12-04 (50)/5	Yes/ 2020-12-04 (50)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3912119; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
Yes/ 2020-10-11 (34)/4	Yes/ 2020-10-08 (31)/4	No	No	Yes/ 2020-10-06 (29)/4	Yes/ 2020-10-08 (31)/4	No	Yes/ 2020-10-06 (29)/4
Subject ID: US3912163; Age (Year): 43; Sex: M; Race: OTHER: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 36.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-13							
Yes/ 2020-12-10 (87)/5	Yes/ 2020-12-10 (87)/5	No	No	Yes/ 2020-12-10 (87)/5	Yes/ 2020-12-10 (87)/5	No	No
Subject ID: US3922006; Age (Year): 62; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 22.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-18/2020-09-15							
Yes/ 2021-01-19 (155)/5	Yes/ 2021-01-19 (155)/5	No	No	Yes/ 2021-01-19 (155)/5	Yes/ 2021-01-19 (155)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3922060; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-02							
Yes/ 2020-12-28 (120)/5	Yes/ 2020-12-28 (120)/5	No	No	Yes/ 2020-12-28 (120)/5	Yes/ 2020-12-28 (120)/5	No	No
Subject ID: US3922142; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-12							
No	No	No	No	Yes/ 2020-12-07 (56)/5	No	No	Yes/ 2020-12-07 (56)/5
Subject ID: US3922160; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-19/2020-11-20							
Yes/ 2021-01-05 (79)/5	Yes/ 2021-01-05 (79)/5	No	No	Yes/ 2021-01-05 (79)/5	Yes/ 2021-01-05 (79)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3922164; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-20/2020-11-24							
Yes/ 2020-12-28 (70)/5	Yes/ 2020-12-28 (70)/5	No	No	Yes/ 2020-12-28 (70)/5	Yes/ 2020-12-28 (70)/5	No	No
Subject ID: US3932049; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-30							
Yes/ 2020-12-23 (114)/5	Yes/ 2020-12-23 (114)/5	No	No	Yes/ 2020-12-23 (114)/5	Yes/ 2020-12-23 (114)/5	No	No
Subject ID: US3932066; Age (Year): 78; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-28							
Yes/ 2020-11-25 (85)/5	Yes/ 2020-11-23 (83)/5	Yes/ 2020-12-01 (91)/5	Yes/ 2020-12-01 (91)/5	Yes/ 2020-11-23 (83)/5	Yes/ 2020-11-23 (83)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3932083; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-08							
Yes/ 2020-11-16 (68)/5	Yes/ 2020-11-16 (68)/5	Yes/ 2020-11-17 (69)/5	Yes/ 2020-11-16 (68)/5	Yes/ 2020-11-16 (68)/5	Yes/ 2020-11-18 (70)/5	No	No
Subject ID: US3932099; Age (Year): 72; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-17							
No	No	No	No	Yes/ 2020-11-03 (55)/5	Yes/ 2020-11-03 (55)/5	No	No
Subject ID: US3932100; Age (Year): 35; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-07							
Yes/ 2020-10-28 (49)/5	Yes/ 2020-11-02 (54)/5	No	No	Yes/ 2020-11-02 (54)/5	Yes/ 2020-11-02 (54)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3932118; Age (Year): 49; Sex: F; Race: MULTIPLE; (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-07							
Yes/ 2021-01-05 (116)/5	Yes/ 2021-01-05 (116)/5	Yes/ 2021-01-16 (127)/5	Yes/ 2021-01-16 (127)/5	Yes/ 2021-01-05 (116)/5	Yes/ 2021-01-05 (116)/5	No	No
Subject ID: US3932120; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-12/2020-10-12							
No	Yes/ 2020-12-02 (82)/5	No	No	Yes/ 2020-12-02 (82)/5	Yes/ 2020-12-02 (82)/5	No	No
Subject ID: US3932144; Age (Year): 78; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-13							
No	No	No	No	Yes/ 2020-12-16 (92)/5	Yes/ 2020-12-16 (92)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3932147; Age (Year): 84; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/							
No	Yes/ 2020-12-17 (93)/3	No	Yes/ 2021-01-03 (110)/3	Yes/ 2020-12-17 (93)/3	Yes/ 2020-12-17 (93)/3	No	No
Subject ID: US3932230; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-07/2020-11-02							
Yes/ 2021-01-06 (92)/5	Yes/ 2021-01-06 (92)/5	No	No	Yes/ 2021-01-06 (92)/5	Yes/ 2021-01-06 (92)/5	No	No
Subject ID: US3932238; Age (Year): 59; Sex: F; Race: MULTIPLE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/							
Yes/ 2020-11-19 (38)/3	Yes/ 2020-11-18 (37)/3	No	No	Yes/ 2020-11-18 (37)/3	Yes/ 2020-11-18 (37)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3932286; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): ; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-17/2020-11-18							
Yes/ 2020-12-01 (46)/4	Yes/ 2020-12-01 (46)/4	Yes/ 2020-12-03 (48)/5	Yes/ 2020-12-03 (48)/5	Yes/ 2020-12-01 (46)/4	Yes/ 2020-12-01 (46)/4	No	No
Subject ID: US3932292; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-19/2020-11-13							
Yes/ 2021-01-15 (89)/5	Yes/ 2021-01-15 (89)/5	No	No	Yes/ 2021-01-15 (89)/5	Yes/ 2021-01-15 (89)/5	No	No
Subject ID: US3932304; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/2020-11-23							
Yes/ 2020-12-07 (48)/5	Yes/ 2020-12-07 (48)/5	No	No	Yes/ 2020-12-07 (48)/5	Yes/ 2020-12-07 (48)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19
COVID-19*		COVID-19*	COVID-19*	COVID-19*	COVID-19*	COVID-19*	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3942079; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/							
Yes/ 2020-09-24 (17)/3	Yes/ 2020-09-24 (17)/3	Yes/ 2020-09-29 (22)/3	Yes/ 2020-09-29 (22)/3	Yes/ 2020-09-29 (22)/3	Yes/ 2020-09-24 (17)/3	Yes/ 2020-09-24 (17)/3	No
Subject ID: US3952033; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/							
Yes/ 2020-10-08 (37)/3	Yes/ 2020-10-08 (37)/3	Yes/ 2020-10-09 (38)/3	Yes/ 2020-10-09 (38)/3	Yes/ 2020-10-09 (38)/3	Yes/ 2020-10-08 (37)/3	Yes/ 2020-10-08 (37)/3	No
Subject ID: US3952094; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-14							
Yes/ 2020-12-24 (101)/5	Yes/ 2020-12-24 (101)/5	Yes/ 2020-12-24 (101)/5	Yes/ 2020-12-24 (101)/5	Yes/ 2020-12-24 (101)/5	Yes/ 2020-12-24 (101)/5	Yes/ 2020-12-24 (101)/5	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3952154; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-25/2020-10-26							
Yes/ 2020-11-19 (56)/5	Yes/ 2020-11-19 (56)/5	No	No	Yes/ 2020-11-19 (56)/5	Yes/ 2020-11-19 (56)/5	No	No
Subject ID: US3962016; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-24							
Yes/ 2020-12-11 (113)/5	Yes/ 2020-12-11 (113)/5	Yes/ 2020-12-21 (123)/5	Yes/ 2020-12-21 (123)/5	Yes/ 2020-12-11 (113)/5	Yes/ 2020-12-11 (113)/5	No	No
Subject ID: US3962026; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
No	No	No	No	Yes/ 2020-10-30 (66)/5	No	No	Yes/ 2020-10-30 (66)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3962037; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-29							
Yes/ 2021-01-07 (130)/5	Yes/ 2021-01-07 (130)/5	No	No	Yes/ 2021-01-07 (130)/5	Yes/ 2021-01-07 (130)/5	No	No
Subject ID: US3962041; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
Yes/ 2020-12-01 (93)/5	Yes/ 2020-12-01 (93)/5	No	No	Yes/ 2020-12-01 (93)/5	Yes/ 2020-12-01 (93)/5	No	No
Subject ID: US3962056; Age (Year): 68; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-09-28							
Yes/ 2020-12-11 (101)/5	Yes/ 2020-12-11 (101)/5	No	No	Yes/ 2020-12-11 (101)/5	Yes/ 2020-12-11 (101)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3962065; Age (Year): 54; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-05							
Yes/ 2020-12-22 (111)/5	Yes/ 2020-12-22 (111)/5	No	No	Yes/ 2020-12-22 (111)/5	Yes/ 2020-12-22 (111)/5	No	No
Subject ID: US3962066; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-01							
Yes/ 2021-01-19 (139)/5	Yes/ 2021-01-19 (139)/5	Yes/ 2021-01-20 (140)/5	Yes/ 2021-01-20 (140)/5	Yes/ 2021-01-19 (139)/5	Yes/ 2021-01-19 (139)/5	No	No
Subject ID: US3962113; Age (Year): 19; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-20/2020-11-18							
Yes/ 2020-11-23 (35)/4	Yes/ 2020-11-23 (35)/4	No	No	Yes/ 2020-11-18 (30)/4	Yes/ 2020-11-18 (30)/4	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3972022; Age (Year): 47; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
No	Yes/ 2020-11-16 (84)/5	No	No	Yes/ 2020-11-09 (77)/5	Yes/ 2020-11-16 (84)/5	No	No
Subject ID: US3972041; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 31.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-11-05 (71)/5	Yes/ 2020-11-05 (71)/5	No	No	Yes/ 2020-11-05 (71)/5	Yes/ 2020-11-05 (71)/5	No	No
Subject ID: US3972106; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 20.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-16/2020-10-19							
Yes/ 2020-12-03 (79)/5	Yes/ 2020-12-15 (91)/5	No	No	Yes/ 2020-12-15 (91)/5	Yes/ 2020-12-15 (91)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3972149; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-14/2020-10-16							
Yes/ 2020-10-23 (40)/4	Yes/ 2020-10-23 (40)/4	No	No	Yes/ 2020-10-23 (40)/4	Yes/ 2020-10-23 (40)/4	No	No
Subject ID: US3972196; Age (Year): 55; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-15							
Yes/ 2020-12-01 (75)/5	Yes/ 2020-12-01 (75)/5	No	No	Yes/ 2020-12-01 (75)/5	Yes/ 2020-12-01 (75)/5	No	No
Subject ID: US3982017; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-10-23 (59)/5	Yes/ 2020-10-23 (59)/5	No	No	Yes/ 2020-10-23 (59)/5	Yes/ 2020-10-23 (59)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3982025; Age (Year): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-12-02 (98)/5	Yes/ 2020-12-02 (98)/5	No	No	Yes/ 2020-12-02 (98)/5	Yes/ 2020-12-02 (98)/5	No	No
Subject ID: US3982075; Age (Year): 45; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	No	No	No	Yes/ 2021-03-18 (199)/5	Yes/ 2021-03-18 (199)/5	No	No
Subject ID: US3982196; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/							
Yes/ 2020-12-15 (90)/3	Yes/ 2020-12-15 (90)/3	No	No	Yes/ 2020-12-15 (90)/3	Yes/ 2020-12-15 (90)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3982256; Age (Year): 46; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-30/2020-10-28							
Yes/ 2020-11-25 (57)/5	Yes/ 2020-11-25 (57)/5	No	No	Yes/ 2020-11-25 (57)/5	Yes/ 2020-11-25 (57)/5	No	No
Subject ID: US3992010; Age (Year): 40; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-19/2020-10-21							
Yes/ 2020-11-12 (55)/5	Yes/ 2020-11-12 (55)/5	No	No	Yes/ 2020-11-12 (55)/5	Yes/ 2020-11-12 (55)/5	No	No
Subject ID: US3992028; Age (Year): 68; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-28							
Yes/ 2020-12-10 (78)/5	Yes/ 2020-12-10 (78)/5	No	No	Yes/ 2020-12-10 (78)/5	Yes/ 2020-12-10 (78)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3992039; Age (Year): 26; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-26/2020-11-03							
Yes/ 2020-11-25 (61)/5	Yes/ 2020-11-25 (61)/5	No	No	Yes/ 2020-11-25 (61)/5	Yes/ 2020-11-25 (61)/5	No	No
Subject ID: US3992076; Age (Year): 40; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-04							
Yes/ 2020-11-24 (48)/5	Yes/ 2020-11-24 (48)/5	No	No	Yes/ 2020-11-24 (48)/5	Yes/ 2020-11-24 (48)/5	No	No
Subject ID: US3992077; Age (Year): 26; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-10							
Yes/ 2020-11-27 (51)/5	Yes/ 2020-11-27 (51)/5	No	No	Yes/ 2020-11-27 (51)/5	Yes/ 2020-11-27 (51)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002081; Age (Year): 33; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-11-16 (106)/5	Yes/ 2020-11-16 (106)/5	No	No	Yes/ 2020-11-16 (106)/5	Yes/ 2020-11-16 (106)/5	No	No
Subject ID: US3002132; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-04							
Yes/ 2020-12-24 (140)/5	Yes/ 2020-12-24 (140)/5	No	No	Yes/ 2020-12-18 (134)/5	Yes/ 2020-12-18 (134)/5	No	No
Subject ID: US3002146; Age (Year): 23; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 39.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-11-19							
No	No	No	No	Yes/ 2020-11-19 (101)/4	No	No	Yes/ 2020-11-19 (101)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Secondary Definition	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3022075; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 44.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-29/2020-09-10							
Yes/2020-12-29 (154)/5	Yes/2020-12-29 (154)/5	No	No	Yes/2020-12-29 (154)/5	Yes/2020-12-29 (154)/5	No	No
Subject ID: US3022136; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-10/2020-09-09							
No	No	No	No	Yes/2020-10-09 (61)/5	No	No	Yes/2020-10-09 (61)/5
Subject ID: US3022167; Age (Year): 21; Sex: F; Race: OTHER: HISPANIC; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 21.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-17/2020-09-14							
No	No	No	No	Yes/2020-09-14 (29)/4	No	No	Yes/2020-09-14 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3022247; Age (Year): 36; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
No	No	No	No	Yes/ 2020-09-18 (29)/4	No	No	Yes/ 2020-09-18 (29)/4
Subject ID: US3032223; Age (Year): 30; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-23							
No	No	No	No	Yes/ 2020-10-19 (62)/5	No	No	No
Subject ID: US3032292; Age (Year): 73; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/2020-09-18							
No	No	No	No	Yes/ 2020-10-13 (54)/5	No	No	Yes/ 2020-10-13 (54)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042072; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/2020-09-02							
Yes/ 2020-11-30 (118)/5	Yes/ 2020-11-30 (118)/5	No	No	Yes/ 2020-11-30 (118)/5	Yes/ 2020-11-30 (118)/5	No	No
Subject ID: US3042243; Age (Year): 65; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
No	No	No	No	Yes/ 2020-10-14 (57)/5	No	No	Yes/ 2020-10-14 (57)/5
Subject ID: US3042314; Age (Year): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/2020-09-25							
No	No	No	No	Yes/ 2020-11-06 (77)/5	No	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3092280; Age (Year): 30; Sex: M; Race: OTHER; HISPANIC; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 39.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	No	No	No	Yes/ 2020-09-29 (29)/4	Yes/ 2020-09-30 (30)/4	No	Yes/ 2020-09-29 (29)/4
Subject ID: US3092299; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 37.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
No	No	No	No	Yes/ 2020-10-30 (57)/5	No	No	Yes/ 2020-10-30 (57)/5
Subject ID: US3162031; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-30/2020-08-27							
Yes/ 2020-10-05 (68)/5	Yes/ 2020-10-06 (69)/5	No	No	Yes/ 2020-10-05 (68)/5	Yes/ 2020-10-05 (68)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162040; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/2020-08-28							
Yes/ 2021-01-01 (155)/5	Yes/ 2021-01-01 (155)/5	No	No	Yes/ 2021-01-01 (155)/5	Yes/ 2021-01-01 (155)/5	No	No
Subject ID: US3162050; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/2020-09-01							
Yes/ 2020-12-28 (147)/5	Yes/ 2020-12-28 (147)/5	No	No	Yes/ 2020-12-28 (147)/5	Yes/ 2020-12-28 (147)/5	No	No
Subject ID: US3162078; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 31.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/							
Yes/ 2020-08-19 (13)/2	Yes/ 2020-08-19 (13)/2	Yes/ 2020-08-29 (23)/3	Yes/ 2020-08-19 (13)/2	Yes/ 2020-08-19 (13)/2	Yes/ 2020-08-19 (13)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3162123; Age (Year): 40; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-16							
Yes/ 2021-01-18 (158)/5	Yes/ 2021-01-18 (158)/5	No	No	Yes/ 2021-01-18 (158)/5	Yes/ 2021-01-18 (158)/5	No	No
Subject ID: US3162182; Age (Year): 69; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
Yes/ 2020-09-23 (30)/4	Yes/ 2020-09-23 (30)/4	No	No	Yes/ 2020-09-22 (29)/4	Yes/ 2020-09-23 (30)/4	No	Yes/ 2020-09-22 (29)/4
Subject ID: US3162302; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 20.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-19							
Yes/ 2020-12-06 (45)/5	Yes/ 2020-12-06 (45)/5	No	No	Yes/ 2020-12-06 (45)/5	Yes/ 2020-12-06 (45)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301 U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC		Based on AC	Severe	Regardless of	Secondary	Death	
Assessments	COVID-19*	Assessments	COVID-19*	Symptomatology and Severity	Definition of COVID-19*	Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3182215; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-07/2020-09-10							
No	No	No	No	Yes/ 2020-09-10 (35)/4	No	No	Yes/ 2020-09-10 (35)/4
Subject ID: US3182283; Age (Year): 31; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-09							
Yes/ 2020-11-24 (106)/5	Yes/ 2020-11-24 (106)/5	No	No	Yes/ 2020-11-24 (106)/5	Yes/ 2020-11-24 (106)/5	No	No
Subject ID: US3192203; Age (Year): 49; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 51.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-11							
Yes/ 2021-01-15 (157)/5	Yes/ 2021-01-15 (157)/5	No	No	Yes/ 2021-01-15 (157)/5	Yes/ 2021-01-15 (157)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3192906; Age (Year): 69; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-19							
Yes/ 2020-12-04 (44)/5	Yes/ 2020-12-04 (44)/5	No	No	Yes/ 2020-12-04 (44)/5	Yes/ 2020-12-04 (44)/5	No	No
Subject ID: US3212179; Age (Year): 61; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-11							
Yes/ 2020-12-29 (138)/5	Yes/ 2020-12-29 (138)/5	No	No	Yes/ 2020-12-29 (138)/5	Yes/ 2020-12-29 (138)/5	No	No
Subject ID: US3212182; Age (Year): 20; Sex: F; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
No	Yes/ 2021-01-28 (168)/3	No	No	Yes/ 2021-01-28 (168)/3	Yes/ 2021-01-28 (168)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301 U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3212390; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-08							
No	No	No	No	Yes/ 2020-10-08 (28)/4	No	No	Yes/ 2020-10-08 (28)/4
Subject ID: US3222117; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 45.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-10							
Yes/ 2020-11-17 (98)/5	Yes/ 2020-11-17 (98)/5	No	Yes/ 2020-12-12 (123)/5	Yes/ 2020-11-17 (98)/5	Yes/ 2020-11-17 (98)/5	No	No
Subject ID: US3222415; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-02							
Yes/ 2021-01-06 (129)/5	Yes/ 2021-01-06 (129)/5	No	No	Yes/ 2021-01-06 (129)/5	Yes/ 2021-01-06 (129)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3242163; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-18							
Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-04 (138)/5	No	No	Yes/ 2021-01-04 (138)/5	Yes/ 2021-01-04 (138)/5	No	No
Subject ID: US3242288; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/							
Yes/ 2020-09-11 (9)/2	Yes/ 2020-09-11 (9)/2	No	No	Yes/ 2020-09-11 (9)/2	Yes/ 2020-09-11 (9)/2	No	No
Subject ID: US3242372; Age (Year): 35; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-21							
No	No	No	No	Yes/ 2020-10-21 (29)/4	No	No	Yes/ 2020-10-21 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3252010; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
No	No	No	No	Yes/ 2020-09-26 (55)/5	No	No	Yes/ 2020-09-26 (55)/5
Subject ID: US3252527; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/							
Yes/ 2020-09-25 (4)/2	Yes/ 2020-09-25 (4)/2	No	No	Yes/ 2020-09-25 (4)/2	Yes/ 2020-09-25 (4)/2	No	No
Subject ID: US3252678; Age (Year): 24; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 26.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-16/2020-11-13							
Yes/ 2020-12-17 (63)/5	Yes/ 2020-12-17 (63)/5	No	No	Yes/ 2020-12-17 (63)/5	Yes/ 2020-12-17 (63)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3262280; Age (Year): 65; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-12/2020-11-06							
No	No	No	No	Yes/ 2020-11-06 (26)/4	No	No	Yes/ 2020-11-06 (26)/4
Subject ID: US3272165; Age (Year): 60; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-15/2020-09-17							
No	No	No	No	Yes/ 2020-09-17 (34)/4	No	No	Yes/ 2020-09-17 (34)/4
Subject ID: US3272203; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
No	No	No	No	Yes/ 2020-11-23 (96)/5	Yes/ 2020-11-28 (101)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3292322; Age (Year): 63; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2021-01-07 (134)/5	Yes/ 2021-01-07 (134)/5	No	No	Yes/ 2021-01-07 (134)/5	Yes/ 2021-01-07 (134)/5	No	No
Subject ID: US3292413; Age (Year): 27; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 27.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/2020-10-22							
Yes/ 2021-01-05 (104)/5	Yes/ 2021-01-05 (104)/5	No	No	Yes/ 2021-01-05 (104)/5	Yes/ 2021-01-05 (104)/5	No	No
Subject ID: US3302182; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-14							
No	No	No	No	Yes/ 2020-10-26 (75)/5	No	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*		Based on AC Assessments	Severe COVID-19*				
Based on AC Assessments	COVID-19*	Based on AC Assessments	COVID-19*				
Subject ID: US3332089; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 32.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/							
Yes/ 2020-09-25 (9)/2	Yes/ 2020-09-25 (9)/2	No	No	Yes/ 2020-09-25 (9)/2	Yes/ 2020-09-25 (9)/2	No	No
Subject ID: US3352075; Age (Year): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-08							
No	No	No	No	Yes/ 2020-10-06 (55)/5	No	No	Yes/ 2020-10-06 (55)/5
Subject ID: US3352498; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-06/							
No	No	No	No	Yes/ 2020-12-10 (66)/3	No	No	Yes/ 2020-12-10 (66)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352501; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 33.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-06/2020-11-03							
No	No	No	No	Yes/ 2020-11-03 (29)/4	No	No	Yes/ 2020-11-03 (29)/4
Subject ID: US3362124; Age (Year): 20; Sex: M; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 27.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/							
Yes/ 2020-08-21 (9)/2	Yes/ 2020-08-21 (9)/2	No	No	Yes/ 2020-08-21 (9)/2	Yes/ 2020-08-21 (9)/2	No	No
Subject ID: US3372273; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 32.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-25							
No	No	No	No	Yes/ 2020-12-28 (124)/5	Yes/ 2020-12-28 (124)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition Caused by COVID-19	
Subject ID: US3382235; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/2020-10-09							
Yes/ 2020-12-04 (86)/5	Yes/ 2020-12-04 (86)/5	No	No	Yes/ 2020-12-04 (86)/5	Yes/ 2020-12-04 (86)/5	No	No
Subject ID: US3392072; Age (Year): 55; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-18							
No	No	No	No	Yes/ 2020-09-18 (26)/4	No	No	Yes/ 2020-09-18 (26)/4
Subject ID: US3392112; Age (Year): 72; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/2020-09-22							
Yes/ 2020-11-09 (74)/5	No	No	No	Yes/ 2020-11-09 (74)/5	No	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3402316; Age (Year): 29; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-09/2020-09-11							
Yes/ 2020-10-14 (67)/5	Yes/ 2020-10-14 (67)/5	No	No	Yes/ 2020-10-14 (67)/5	Yes/ 2020-10-14 (67)/5	No	No
Subject ID: US3402466; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-22/2020-11-19							
No	No	No	No	Yes/ 2020-11-19 (29)/4	No	No	Yes/ 2020-11-19 (29)/4
Subject ID: US3412129; Age (Year): 37; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-05/							
Yes/ 2020-08-24 (20)/3	Yes/ 2020-08-24 (20)/3	No	No	Yes/ 2020-08-24 (20)/3	Yes/ 2020-08-24 (20)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3422172; Age (Year): 39; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	Yes/ 2020-12-14 (105)/5	No	No	Yes/ 2020-12-14 (105)/5	Yes/ 2020-12-14 (105)/5	No	No
Subject ID: US3432615; Age (Year): 49; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 40.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-16/2020-11-10							
Yes/ 2021-01-02 (79)/5	Yes/ 2021-01-02 (79)/5	No	No	Yes/ 2021-01-02 (79)/5	Yes/ 2021-01-02 (79)/5	No	No
Subject ID: US3442041; Age (Year): 64; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/2020-09-17							
Yes/ 2020-12-22 (125)/5	Yes/ 2020-12-22 (125)/5	No	No	Yes/ 2020-12-22 (125)/5	Yes/ 2020-12-22 (125)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3442122; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-09-28							
Yes/ 2020-12-16 (105)/5	Yes/ 2020-12-16 (105)/5	No	No	Yes/ 2020-12-16 (105)/5	Yes/ 2020-12-16 (105)/5	No	No
Subject ID: US3452127; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
Yes/ 2020-10-13 (72)/5	Yes/ 2020-10-13 (72)/5	No	No	Yes/ 2020-10-13 (72)/5	Yes/ 2020-10-13 (72)/5	No	No
Subject ID: US3452155; Age (Year): 41; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 79.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-08-31							
No	No	No	No	Yes/ 2020-08-31 (29)/4	No	No	Yes/ 2020-08-31 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3452262; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-10							
No	No	No	No	Yes/ 2020-09-10 (36)/4	No	No	Yes/ 2020-09-10 (36)/4
Subject ID: US3472002; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-09-28							
No	No	No	No	Yes/ 2020-10-26 (57)/5	No	No	Yes/ 2020-10-26 (57)/5
Subject ID: US3472033; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/2020-10-09							
Yes/ 2021-01-06 (118)/5	Yes/ 2021-01-06 (118)/5	No	No	Yes/ 2021-01-06 (118)/5	Yes/ 2021-01-06 (118)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3482049; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/2020-09-10							
Yes/ 2021-01-14 (154)/5	Yes/ 2021-01-14 (154)/5	No	No	Yes/ 2021-01-14 (154)/5	Yes/ 2021-01-14 (154)/5	No	No
Subject ID: US3482143; Age (Year): 32; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
No	No	No	No	Yes/ 2020-09-23 (29)/4	No	No	Yes/ 2020-09-23 (29)/4
Subject ID: US3482227; Age (Year): 34; Sex: F; Race: MULTIPLE: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
Yes/ 2021-01-07 (126)/5	Yes/ 2021-01-07 (126)/5	No	No	Yes/ 2020-12-30 (118)/5	Yes/ 2020-12-30 (118)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3482287; Age (Year): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/2020-11-17							
No	No	No	No	Yes/ 2020-11-17 (36)/4	No	No	Yes/ 2020-11-17 (36)/4
Subject ID: US3482304; Age (Year): 53; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-19/2020-11-16							
Yes/ 2020-11-30 (43)/5	Yes/ 2020-11-30 (43)/5	No	No	Yes/ 2020-11-30 (43)/5	Yes/ 2020-11-30 (43)/5	No	No
Subject ID: US3492208; Age (Year): 44; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 44.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/2020-10-16							
No	No	No	No	Yes/ 2020-10-16 (29)/4	No	No	Yes/ 2020-10-16 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3492243; Age (Year): 50; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-23/2020-10-21							
No	No	No	No	Yes/ 2020-11-11 (50)/5	Yes/ 2020-11-18 (57)/5	No	No
Subject ID: US3522313; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
No	No	No	No	Yes/ 2020-12-21 (120)/5	No	No	No
Subject ID: US3532259; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-07							
Yes/ 2020-10-29 (51)/5	Yes/ 2020-10-29 (51)/5	No	No	Yes/ 2020-10-29 (51)/5	Yes/ 2020-10-29 (51)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection				
COVID-19*		COVID-19*		Regardless of	Secondary	Death	Asymptomatic
Based on AC		Based on AC	Severe	Symptomatology	Definition	Caused by	SARS-CoV-2
Assessments	COVID-19*	Assessments	COVID-19*	and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3532279; Age (Year): 66; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2020-10-08	2020-10-08			2020-10-08	2020-10-08		
(29)/3	(29)/3			(29)/3	(29)/3		
Subject ID: US3552482; Age (Year): 59; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 41.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/2020-10-20							
No	No	No	No	Yes/	No	No	Yes/
				2020-10-20			2020-10-20
				(29)/4			(29)/4
Subject ID: US3562081; Age (Year): 51; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 17.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-21							
No	Yes/	No	No	Yes/	Yes/	No	No
	2020-09-21			2020-09-21	2020-09-21		
	(27)/4			(27)/4	(27)/4		

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301 U\BLA\TLF\l1602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3572030; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-21							
Yes/ 2020-12-16 (120)/5	Yes/ 2020-12-16 (120)/5	No	No	Yes/ 2020-12-16 (120)/5	Yes/ 2020-12-16 (120)/5	No	No
Subject ID: US3582081; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-28							
No	Yes/ 2020-09-29 (29)/4	No	No	Yes/ 2020-09-28 (28)/4	Yes/ 2020-09-29 (29)/4	No	Yes/ 2020-09-28 (28)/4
Subject ID: US3582110; Age (Year): 41; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 48.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-21/2020-10-19							
Yes/ 2021-01-14 (116)/5	Yes/ 2021-01-14 (116)/5	No	No	Yes/ 2021-01-14 (116)/5	Yes/ 2021-01-14 (116)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3592197; Age (Year): 44; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-16/2020-09-14							
No	No	No	No	Yes/ 2020-09-14 (30)/4	No	No	Yes/ 2020-09-14 (30)/4
Subject ID: US3632047; Age (Year): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
No	No	No	No	Yes/ 2020-10-30 (57)/5	No	No	Yes/ 2020-10-30 (57)/5
Subject ID: US3632119; Age (Year): 51; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/2020-11-03							
Yes/ 2020-12-02 (56)/5	Yes/ 2020-12-02 (56)/5	No	No	Yes/ 2020-12-02 (56)/5	Yes/ 2020-12-02 (56)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]											
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*		Death Caused by COVID-19		Asymptomatic SARS-CoV-2 Infection	
COVID-19*		COVID-19*		COVID-19*		COVID-19*		COVID-19		COVID-19	
Subject ID: US3652038; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 20.8; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-25/											
No	No	No	No	Yes/ 2020-10-27 (33)/3	Yes/ 2020-10-27 (33)/3	No	No				
Subject ID: US3672074; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 37.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-11											
Yes/ 2020-12-28 (139)/5	Yes/ 2020-12-28 (139)/5	No	No	Yes/ 2020-12-28 (139)/5	Yes/ 2020-12-28 (139)/5	No	No				
Subject ID: US3692160; Age (Year): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-28/2020-10-28											
No	No	No	No	Yes/ 2020-10-28 (31)/4	No	No	Yes/ 2020-10-28 (31)/4				

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3702010; Age (Year): 74; Sex: M; Race: UNKNOWN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/							
Yes/ 2021-01-08 (127)/3	Yes/ 2021-01-08 (127)/3	Yes/ 2021-01-08 (127)/3	Yes/ 2021-01-08 (127)/3	Yes/ 2021-01-08 (127)/3	Yes/ 2021-01-08 (127)/3	Yes/ 2021-02-25 (175)/3	No
Subject ID: US3712058; Age (Year): 70; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/2020-10-13							
Yes/ 2020-11-16 (63)/5	Yes/ 2020-11-16 (63)/5	No	No	Yes/ 2020-11-16 (63)/5	Yes/ 2020-11-16 (63)/5	No	No
Subject ID: US3712246; Age (Year): 33; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 42.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-20							
No	No	No	No	Yes/ 2020-11-20 (29)/4	No	No	Yes/ 2020-11-20 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3712281; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-23							
Yes/ 2021-01-08 (78)/5	Yes/ 2021-01-08 (78)/5	No	No	Yes/ 2021-01-08 (78)/5	Yes/ 2021-01-08 (78)/5	No	No
Subject ID: US3722125; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-02							
Yes/ 2020-12-08 (125)/5	Yes/ 2020-12-08 (125)/5	No	No	Yes/ 2020-12-08 (125)/5	Yes/ 2020-12-08 (125)/5	No	No
Subject ID: US3722317; Age (Year): 45; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-15							
No	No	No	No	Yes/ 2020-10-23 (66)/5	No	No	Yes/ 2020-10-23 (66)/5

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3732202; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-25							
Yes/ 2020-11-13 (79)/5	Yes/ 2020-11-13 (79)/5	No	No	Yes/ 2020-11-13 (79)/5	Yes/ 2020-11-13 (79)/5	No	No
Subject ID: US3732399; Age (Year): 32; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-19/2020-11-16							
Yes/ 2020-12-23 (66)/5	Yes/ 2020-12-23 (66)/5	No	No	Yes/ 2020-12-23 (66)/5	Yes/ 2020-12-23 (66)/5	No	No
Subject ID: US3742070; Age (Year): 39; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-27/2020-09-24							
Yes/ 2020-12-18 (114)/5	Yes/ 2020-12-18 (114)/5	No	No	Yes/ 2020-12-18 (114)/5	Yes/ 2020-12-18 (114)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3742357; Age (Year): 53; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-17/2020-10-15							
Yes/	Yes/	Yes/	Yes/	Yes/	Yes/	No	No
2020-12-28	2020-12-28	2021-01-01	2021-01-01	2020-12-28	2020-12-28		
(103)/5	(103)/5	(107)/5	(107)/5	(103)/5	(103)/5		
Subject ID: US3752163; Age (Year): 61; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 35.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/2020-09-16							
No	No	No	No	Yes/	No	No	Yes/
				2020-10-14			2020-10-14
				(57)/5			(57)/5
Subject ID: US3752393; Age (Year): 74; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.8; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-03/2020-10-07							
Yes/	Yes/	No	No	Yes/	Yes/	No	No
2021-01-06	2021-01-06			2021-01-05	2021-01-05		
(126)/5	(126)/5			(125)/5	(125)/5		

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3772037; Age (Year): 72; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/2020-09-08							
Yes/ 2020-11-05 (87)/5	Yes/ 2020-11-07 (89)/5	Yes/ 2020-11-08 (90)/5	Yes/ 2020-11-07 (89)/5	Yes/ 2020-11-06 (88)/5	Yes/ 2020-11-07 (89)/5	No	No
Subject ID: US3772064; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/2020-09-14							
Yes/ 2020-11-11 (91)/5	Yes/ 2020-11-11 (91)/5	No	No	Yes/ 2020-11-11 (91)/5	Yes/ 2020-11-11 (91)/5	No	No
Subject ID: US3812148; Age (Year): 30; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 20.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/2020-09-09							
Yes/ 2021-01-07 (149)/5	Yes/ 2021-01-07 (149)/5	No	No	Yes/ 2021-01-07 (149)/5	Yes/ 2021-01-07 (149)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3812263; Age (Year): 72; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/2020-09-23							
Yes/ 2020-11-12 (79)/5	Yes/ 2020-11-12 (79)/5	No	No	Yes/ 2020-11-12 (79)/5	Yes/ 2020-11-12 (79)/5	No	No
Subject ID: US3812306; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/2020-10-02							
Yes/ 2020-11-25 (85)/5	Yes/ 2020-11-25 (85)/5	No	No	Yes/ 2020-11-25 (85)/5	Yes/ 2020-11-25 (85)/5	No	No
Subject ID: US3812317; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-04/2020-10-02							
Yes/ 2020-12-22 (110)/5	Yes/ 2020-12-22 (110)/5	No	No	Yes/ 2020-12-22 (110)/5	Yes/ 2020-12-22 (110)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3832030; Age (Year): 47; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 32.3; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-01/2020-08-29							
No	No	No	No	Yes/ 2020-08-29 (29)/4	No	No	Yes/ 2020-08-29 (29)/4
Subject ID: US3832119; Age (Year): 59; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/2020-09-03							
Yes/ 2020-12-02 (119)/5	Yes/ 2020-12-02 (119)/5	No	No	Yes/ 2020-12-02 (119)/5	Yes/ 2020-12-02 (119)/5	No	No
Subject ID: US3832274; Age (Year): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 43.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-29/2020-10-28							
Yes/ 2020-12-29 (92)/5	Yes/ 2020-12-29 (92)/5	No	No	Yes/ 2020-12-29 (92)/5	Yes/ 2020-12-29 (92)/5	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3852132; Age (Year): 38; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-06							
Yes/ 2020-12-27 (110)/5	Yes/ 2020-12-27 (110)/5	No	No	Yes/ 2020-12-18 (101)/5	Yes/ 2020-12-18 (101)/5	No	No
Subject ID: US3862278; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 24.1; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-01/2020-10-29							
No	No	No	No	Yes/ 2020-10-29 (29)/4	No	No	Yes/ 2020-10-29 (29)/4
Subject ID: US3872030; Age (Year): 43; Sex: M; Race: MULTIPLE: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.4; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/2020-09-09							
No	No	No	No	Yes/ 2020-09-09 (38)/4	No	No	Yes/ 2020-09-09 (38)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3872409; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-01/2020-09-29							
Yes/ 2020-12-08 (99)/5	Yes/ 2020-12-08 (99)/5	No	No	Yes/ 2020-12-08 (99)/5	Yes/ 2020-12-08 (99)/5	No	No
Subject ID: US3882019; Age (Year): 74; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.2; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/2020-10-08							
No	No	No	No	Yes/ 2020-12-22 (105)/5	No	No	No
Subject ID: US3882049; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.2; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/							
Yes/ 2020-11-25 (34)/3	Yes/ 2020-11-25 (34)/3	No	No	Yes/ 2020-11-25 (34)/3	Yes/ 2020-11-25 (34)/3	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*		SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3882058; Age (Year): 58; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-23/2020-11-23							
No	No	No	No	Yes/ 2020-11-23 (32)/4	No	No	Yes/ 2020-11-23 (32)/4
Subject ID: US3892017; Age (Year): 31; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.7; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/2020-10-02							
Yes/ 2020-11-20 (82)/5	Yes/ 2020-11-20 (82)/5	No	No	Yes/ 2020-11-20 (82)/5	Yes/ 2020-11-20 (82)/5	No	No
Subject ID: US3912001; Age (Year): 66; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 50.9; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/2020-09-22							
No	No	No	No	Yes/ 2020-09-22 (29)/4	No	No	Yes/ 2020-09-22 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3942150; Age (Year): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.5; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-12/2020-11-06							
No	No	No	No	Yes/ 2020-12-03 (53)/5	No	No	Yes/ 2020-12-03 (53)/5
Subject ID: US3962019; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 31.0; PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-24/2020-09-21							
No	No	No	No	Yes/ 2020-10-19 (57)/5	No	No	Yes/ 2020-10-19 (57)/5
Subject ID: US3972225; Age (Year): 22; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 30.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-12/							
Yes/ 2020-10-21 (10)/2	Yes/ 2020-10-21 (10)/2	No	No	Yes/ 2020-10-21 (10)/2	Yes/ 2020-10-21 (10)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Negative; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection

Subject ID: US3992036; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.2;
PP Set: Yes; Baseline RT-PCR: Negative; Baseline Elecsys: Negative; Date of First/Second Injection:
2020-09-26/2020-10-27

No	No	No	No	Yes/ 2020-10-27 (32)/4	No	No	Yes/ 2020-10-27 (32)/4
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Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*		Based on AC Assessments	Severe COVID-19*				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3002352; Age (Year): 20; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 36.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-08/							
No	No	No	No	Yes/ 2020-11-05 (29) / 3	No	No	Yes/ 2020-11-05 (29) / 3
Subject ID: US3002356; Age (Year): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 41.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-09/2020-11-06							
No	No	No	No	Yes/ 2020-11-06 (29) / 4	No	No	Yes/ 2020-11-06 (29) / 4
Subject ID: US3042063; Age (Year): 21; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 27.5; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/							
No	No	No	No	Yes/ 2020-08-07 (4) / 2	Yes/ 2020-08-07 (4) / 2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3042150; Age (Year): 34; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 27.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-12/							
No	Yes/ 2020-08-14 (3)/2	No	No	Yes/ 2020-08-14 (3)/2	Yes/ 2020-08-14 (3)/2	No	No
Subject ID: US3142145; Age (Year): 54; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 47.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-07/							
No	No	No	No	Yes/ 2020-09-08 (33)/3	No	No	Yes/ 2020-09-08 (33)/3
Subject ID: US3162159; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 19.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/							
Yes/ 2020-08-27 (8)/2	Yes/ 2020-08-27 (8)/2	Yes/ 2020-09-01 (13)/2	Yes/ 2020-08-29 (10)/2	Yes/ 2020-08-27 (8)/2	Yes/ 2020-08-27 (8)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection				
COVID-19*		COVID-19*		Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3172026; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 33.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/							
No	No	No	No	Yes/ 2020-09-08 (29)/3	No	No	Yes/ 2020-09-08 (29)/3
Subject ID: US3172332; Age (Year): 51; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 23.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-25/2020-09-22							
No	No	No	No	Yes/ 2020-09-22 (29)/4	No	No	Yes/ 2020-09-22 (29)/4
Subject ID: US3172440; Age (Year): 64; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.5; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-20/							
No	No	No	No	Yes/ 2020-11-18 (30)/3	No	No	Yes/ 2020-11-18 (30)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3172467; Age (Year): 55; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 27.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/							
No	No	No	No	Yes/ 2020-11-18 (29)/3	No	No	Yes/ 2020-11-18 (29)/3
Subject ID: US3182279; Age (Year): 24; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 21.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-11/							
No	No	No	No	Yes/ 2020-09-10 (31)/3	No	No	Yes/ 2020-09-10 (31)/3
Subject ID: US3212066; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 26.4; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/							
Yes/ 2020-08-14 (9)/2	Yes/ 2020-08-14 (9)/2	No	No	Yes/ 2020-08-14 (9)/2	Yes/ 2020-08-14 (9)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3212087; Age (Year): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 26.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-07/							
No	No	No	No	Yes/ 2020-09-04 (29)/3	No	No	Yes/ 2020-09-04 (29)/3
Subject ID: US3242076; Age (Year): 20; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-13/2020-09-16							
No	No	No	No	Yes/ 2020-10-14 (63)/5	No	No	No
Subject ID: US3252318; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 34.5; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-24/							
No	No	No	No	Yes/ 2020-09-22 (30)/3	No	No	Yes/ 2020-09-22 (30)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3302384; Age (Year): 22; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.4; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-26/							
No	No	No	No	Yes/ 2020-09-23 (29)/3	No	No	Yes/ 2020-09-23 (29)/3
Subject ID: US3312020; Age (Year): 73; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/							
No	No	No	No	Yes/ 2020-09-08 (29)/3	No	No	Yes/ 2020-09-08 (29)/3
Subject ID: US3312049; Age (Year): 52; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 34.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-12/							
No	No	No	No	Yes/ 2020-09-09 (29)/3	No	No	Yes/ 2020-09-09 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]											
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments		SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*		Death Caused by COVID-19		Asymptomatic SARS-CoV-2 Infection	
COVID-19*		COVID-19*		COVID-19*		COVID-19*		COVID-19		COVID-19	
(b) (6)				35; Sex: M; Race: MULTIPLE: (b) (6)							
(b) (6)				Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-21/							
No	No	No	No	Yes/ 2020-09-18 (29)/3	No	No	No	Yes/ 2020-09-18 (29)/3			
Subject ID: US3312583; Age (Year): 20; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 22.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/											
No	No	No	No	Yes/ 2020-10-07 (29)/3	No	No	No	Yes/ 2020-10-07 (29)/3			
Subject ID: US3352410; Age (Year): 74; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 29.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/											
No	No	No	No	Yes/ 2020-10-22 (29)/3	No	No	No	Yes/ 2020-10-22 (29)/3			

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3372092; Age (Year): 68; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-19/							
No	No	No	No	Yes/ 2020-09-18 (31)/3	No	No	Yes/ 2020-09-18 (31)/3
Subject ID: US3382035; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 30.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
No	Yes/ 2020-08-29 (16)/3	No	No	Yes/ 2020-08-24 (11)/2	Yes/ 2020-08-24 (11)/2	No	No
Subject ID: US3392240; Age (Year): 63; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 28.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/							
No	No	No	No	Yes/ 2020-10-07 (27)/3	No	No	Yes/ 2020-10-07 (27)/3

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19* Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3402446; Age (Year): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-16/							
No	No	No	No	Yes/ 2020-11-13 (29)/3	No	No	Yes/ 2020-11-13 (29)/3
Subject ID: US3402452; Age (Year): 57; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/							
No	No	No	No	Yes/ 2020-11-24 (35)/3	No	No	Yes/ 2020-11-24 (35)/3
Subject ID: US3412087; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.3; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-31/							
No	No	No	No	Yes/ 2020-08-28 (29)/3	No	No	Yes/ 2020-08-28 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3452295; Age (Year): 62; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-06/							
Yes/ 2020-08-10 (5)/2	Yes/ 2020-08-10 (5)/2	No	No	Yes/ 2020-08-10 (5)/2	Yes/ 2020-08-10 (5)/2	No	No
Subject ID: US3492295; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 22.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-09/							
No	No	No	No	Yes/ 2020-11-06 (29)/3	No	No	Yes/ 2020-11-06 (29)/3
Subject ID: US3522353; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-25/							
No	No	No	No	Yes/ 2020-09-23 (30)/3	No	No	Yes/ 2020-09-23 (30)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection		Death	Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3522637; Age (Year): 52; Sex: F; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 23.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-09/							
No	No	No	No	Yes/ 2020-10-07 (29)/3	No	No	Yes/ 2020-10-07 (29)/3
Subject ID: US3552530; Age (Year): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 35.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-10-14/							
Yes/ 2020-10-20 (7)/2	Yes/ 2020-10-23 (10)/2	No	No	Yes/ 2020-10-23 (10)/2	Yes/ 2020-10-23 (10)/2	No	No
Subject ID: US3572042; Age (Year): 29; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 27.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-20/							
No	No	No	No	Yes/ 2020-09-21 (33)/3	No	No	Yes/ 2020-09-21 (33)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
		Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity		Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
COVID-19*		Based on AC Assessments	Severe COVID-19*				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*				
Subject ID: US3592196; Age (Year): 69; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-16/							
No	No	No	No	Yes/ 2020-09-13 (29)/3	No	No	Yes/ 2020-09-13 (29)/3
Subject ID: US3622118; Age (Year): 74; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 35.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-31/2020-09-28							
No	No	No	No	Yes/ 2020-09-28 (29)/4	No	No	Yes/ 2020-09-28 (29)/4
Subject ID: US3642257; Age (Year): 56; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-19/							
No	No	No	No	Yes/ 2020-10-17 (29)/3	No	No	Yes/ 2020-10-17 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3662136; Age (Year): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.0; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-25/2020-10-23							
No	No	No	No	Yes/ 2020-12-31 (98)/5	No	No	No
Subject ID: US3722237; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 38.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-13/2020-09-10							
No	No	No	No	Yes/ 2020-09-10 (29)/4	No	No	Yes/ 2020-09-10 (29)/4
Subject ID: US3802225; Age (Year): 19; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 22.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-11/							
No	No	No	No	Yes/ 2020-11-23 (74)/3	No	No	Yes/ 2020-11-23 (74)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: Placebo

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3812257; Age (Year): 52; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 52.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-25/							
No	No	No	No	Yes/ 2020-09-23 (30)/3	No	No	Yes/ 2020-09-23 (30)/3
Subject ID: US3862272; Age (Year): 31; Sex: F; Race: NOT REPORTED; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-10-02/							
No	No	No	No	Yes/ 2020-11-05 (35)/3	No	No	Yes/ 2020-11-05 (35)/3
Subject ID: US3952175; Age (Year): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 40.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-29/2020-10-29							
No	No	No	No	Yes/ 2020-10-29 (31)/4	No	No	Yes/ 2020-10-29 (31)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3002257; Age (Year): 23; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 23.5; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-08/2020-10-06							
No	No	No	No	Yes/ 2020-10-06 (29)/4	No	No	Yes/ 2020-10-06 (29)/4
Subject ID: US3012118; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.3; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-12/							
No	No	No	No	Yes/ 2020-09-09 (29)/3	No	No	Yes/ 2020-09-09 (29)/3
Subject ID: US3012253; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 33.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-01/2020-09-29							
No	No	No	No	Yes/ 2020-09-29 (29)/4	No	No	Yes/ 2020-09-29 (29)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3012352; Age (Year): 37; Sex: M; Race: ASIAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-10-20/							
No	No	No	No	Yes/ 2020-11-17 (29)/3	No	No	Yes/ 2020-11-17 (29)/3
Subject ID: US3022012; Age (Year): 35; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 33.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-07-27/							
No	No	No	No	Yes/ 2020-08-04 (9)/2	Yes/ 2020-08-05 (10)/2	No	No
Subject ID: US3052191; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 29.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-13/							
No	No	No	No	Yes/ 2020-09-23 (42)/3	No	No	Yes/ 2020-09-23 (42)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3052219; Age (Year): 56; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 42.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-14/							
No	No	No	No	Yes/ 2020-09-08 (26)/3	No	No	Yes/ 2020-09-08 (26)/3
Subject ID: US3062235; Age (Year): 48; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-14/							
No	No	No	No	Yes/ 2020-09-11 (29)/3	No	No	Yes/ 2020-09-11 (29)/3
Subject ID: US3152492; Age (Year): 21; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 29.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-10-15/							
No	No	No	No	Yes/ 2020-11-19 (36)/3	No	No	Yes/ 2020-11-19 (36)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3172014; Age (Year): 38; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 26.3; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-10/							
No	No	No	No	Yes/ 2020-09-04 (26)/3	No	No	Yes/ 2020-09-04 (26)/3
Subject ID: US3172035; Age (Year): 45; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 27.3; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-11/2020-09-08							
No	No	No	No	Yes/ 2020-09-08 (29)/4	No	No	Yes/ 2020-09-08 (29)/4
Subject ID: US3172298; Age (Year): 48; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-24/							
No	No	No	No	Yes/ 2020-09-25 (33)/3	No	No	Yes/ 2020-09-25 (33)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3172443; Age (Year): 58; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-10-21/							
No	Yes/ 2020-10-28 (8)/2	No	No	Yes/ 2020-10-28 (8)/2	Yes/ 2020-10-28 (8)/2	No	No
Subject ID: US3172464; Age (Year): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 19.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/							
No	No	No	No	Yes/ 2020-11-18 (29)/3	No	No	Yes/ 2020-11-18 (29)/3
Subject ID: US3172466; Age (Year): 70; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 34.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-21/							
No	No	No	No	Yes/ 2020-11-18 (29)/3	No	No	Yes/ 2020-11-18 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3182280; Age (Year): 26; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 21.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-11/							
No	No	No	No	Yes/ 2020-09-10 (31)/3	No	No	Yes/ 2020-09-10 (31)/3
Subject ID: US3212005; Age (Year): 43; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 25.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-03/							
No	No	No	No	Yes/ 2020-08-31 (29)/3	No	No	Yes/ 2020-08-31 (29)/3
Subject ID: US3212016; Age (Year): 49; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-03/							
Yes/ 2020-08-03 (1)/2	Yes/ 2020-08-07 (5)/2	No	No	Yes/ 2020-08-07 (5)/2	Yes/ 2020-08-07 (5)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3252075; Age (Year): 67; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 27.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-07/							
Yes/ 2020-08-13 (7)/2	Yes/ 2020-08-13 (7)/2	No	No	Yes/ 2020-08-13 (7)/2	Yes/ 2020-08-13 (7)/2	No	No
Subject ID: US3262062; Age (Year): 61; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 26.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-07-31/							
No	No	No	No	Yes/ 2020-09-04 (36)/3	No	No	Yes/ 2020-09-04 (36)/3
Subject ID: US3262084; Age (Year): 50; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 25.9; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-04/2020-09-02							
No	No	No	No	Yes/ 2020-09-02 (30)/4	No	No	Yes/ 2020-09-02 (30)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3262219; Age (Year): 42; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 37.4; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/							
No	No	No	No	Yes/ 2020-09-21 (33)/3	No	No	Yes/ 2020-09-21 (33)/3
Subject ID: US3272180; Age (Year): 32; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 28.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-18/							
No	No	No	No	Yes/ 2020-09-15 (29)/3	No	No	Yes/ 2020-09-15 (29)/3
Subject ID: US3272260; Age (Year): 30; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 37.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-22/							
No	No	No	No	Yes/ 2020-08-28 (7)/2	Yes/ 2020-08-28 (7)/2	No	No

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3292412; Age (Year): 42; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 47.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-24/							
Yes/ 2020-09-28 (5)/2	Yes/ 2020-09-28 (5)/2	No	No	Yes/ 2020-09-27 (4)/2	Yes/ 2020-09-27 (4)/2	No	No
Subject ID: US3312409; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-31/							
No	No	No	No	Yes/ 2020-09-28 (29)/3	No	No	Yes/ 2020-09-28 (29)/3
Subject ID: US3312584; Age (Year): 20; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 20.2; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-09/							
No	No	No	No	Yes/ 2020-10-07 (29)/3	No	No	Yes/ 2020-10-07 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection		Secondary	Death	Asymptomatic
Based on AC		Based on AC	Severe	Regardless of	Definition	Caused by	SARS-CoV-2
Assessments	COVID-19*	Assessments	COVID-19*	Symptomatology and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3342198; Age (Year): 46; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 40.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-04/							
No	No	No	No	Yes/ 2020-10-01 (28)/3	No	No	Yes/ 2020-10-01 (28)/3
Subject ID: US3342326; Age (Year): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 26.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-12/							
No	No	No	No	Yes/ 2020-11-09 (29)/3	No	No	Yes/ 2020-11-09 (29)/3
Subject ID: US3352143; Age (Year): 19; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 24.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-20/							
No	No	No	No	Yes/ 2020-09-19 (31)/3	No	No	Yes/ 2020-09-19 (31)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3352151; Age (Year): 31; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.7; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-20/							
No	No	No	No	Yes/ 2020-09-22 (34)/3	No	No	Yes/ 2020-09-22 (34)/3
Subject ID: US3352331; Age (Year): 27; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 25.4; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-10/							
No	No	No	No	Yes/ 2020-10-08 (29)/3	No	No	Yes/ 2020-10-08 (29)/3
Subject ID: US3442211; Age (Year): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 32.4; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-05/							
No	No	No	No	Yes/ 2020-10-30 (26)/3	No	No	Yes/ 2020-10-30 (26)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19* Based on AC Assessments	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3452200; Age (Year): 56; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-04/							
No	No	No	No	Yes/ 2020-09-02 (30)/3	No	No	Yes/ 2020-09-02 (30)/3
Subject ID: US3492237; Age (Year): 60; Sex: M; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m ²): 35.6; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-22/							
Yes/ 2020-09-28 (7)/2	Yes/ 2020-09-28 (7)/2	No	No	Yes/ 2020-09-28 (7)/2	Yes/ 2020-09-28 (7)/2	No	No
Subject ID: US3502203; Age (Year): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-13/							
No	No	No	No	Yes/ 2020-11-10 (29)/3	No	No	Yes/ 2020-11-10 (29)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19* Based on AC Assessments		Severe COVID-19* Based on AC Assessments	Severe COVID-19*	SARS-CoV-2 Infection Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3662135; Age (Year): 48; Sex: M; Race: OTHER: (b) (6) Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 47.5; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-24/2020-10-22							
No	No	No	No	Yes/ 2020-10-22 (29)/4	No	No	Yes/ 2020-10-22 (29)/4
Subject ID: US3672261; Age (Year): 27; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-21/							
No	No	No	No	Yes/ 2020-09-22 (33)/3	No	No	Yes/ 2020-09-22 (33)/3
Subject ID: US3712041; Age (Year): 21; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 23.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-10/							
No	No	No	No	Yes/ 2020-10-06 (27)/3	No	No	Yes/ 2020-10-06 (27)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*	SARS-CoV-2 Infection				
Based on AC Assessments	COVID-19*	Based on AC Assessments	Severe COVID-19*	Regardless of Symptomatology and Severity	Secondary Definition of COVID-19*	Death Caused by COVID-19	Asymptomatic SARS-CoV-2 Infection
Subject ID: US3712209; Age (Year): 59; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 30.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-15/							
No	No	No	No	Yes/ 2020-11-12 (29)/3	No	No	Yes/ 2020-11-12 (29)/3
Subject ID: US3732262; Age (Year): 37; Sex: F; Race: WHITE; Ethnicity: HISPANIC OR LATINO; BMI (kg/m²): 31.1; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-02/							
Yes/ 2020-09-17 (16)/3	Yes/ 2020-09-17 (16)/3	No	No	Yes/ 2020-09-10 (9)/2	Yes/ 2020-09-10 (9)/2	No	No
Subject ID: US3742416; Age (Year): 43; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 24.3; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-18/							
No	No	No	No	Yes/ 2020-11-13 (57)/3	No	No	Yes/ 2020-11-13 (57)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe	SARS-CoV-2				
Based on AC		COVID-19*	Infection				
Assessments	COVID-19*	Based on AC	Severe	Regardless of	Secondary	Death	Asymptomatic
		Assessments	COVID-19*	Symptomatology	Definition	Caused by	SARS-CoV-2
				and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3752306; Age (Year): 54; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 25.7; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-28/2020-09-25							
No	No	No	No	Yes/ 2020-09-25 (29)/4	No	No	Yes/ 2020-09-25 (29)/4
Subject ID: US3802254; Age (Year): 20; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 24.0; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-09-15/							
No	No	No	No	Yes/ 2020-10-15 (31)/3	No	No	Yes/ 2020-10-15 (31)/3
Subject ID: US3812293; Age (Year): 51; Sex: F; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m ²): 36.3; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-08-28/							
No	No	No	No	Yes/ 2020-09-28 (32)/3	No	No	Yes/ 2020-09-28 (32)/3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
COVID-19*		Severe COVID-19*		SARS-CoV-2 Infection		Asymptomatic	
Based on AC		Based on AC	Severe	Regardless of	Secondary	Death	
Assessments	COVID-19*	Assessments	COVID-19*	Symptomatology and Severity	Definition of COVID-19*	Caused by COVID-19	SARS-CoV-2 Infection
Subject ID: US3832216; Age (Year): 24; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 33.5; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-08-19/							
No	No	No	No	Yes/ 2020-09-16 (29) /3	No	No	Yes/ 2020-09-16 (29) /3
Subject ID: US3862164; Age (Year): 41; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 28.6; PP Set: No; Baseline RT-PCR: Negative; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-10/2020-10-08							
No	No	No	No	Yes/ 2020-10-08 (29) /4	No	No	Yes/ 2020-10-08 (29) /4
Subject ID: US3872416; Age (Year): 36; Sex: M; Race: MULTIPLE: (b) (6) Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 37.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-02/							
No	No	No	No	Yes/ 2020-10-13 (42) /3	No	No	Yes/ 2020-10-13 (42) /3

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

Baseline SARS-CoV-2 Status: Positive; Treatment Group: mRNA-1273

Case/Date of Case (Rel Day)/Time Window [1]							
		SARS-CoV-2					
		Infection					
COVID-19*		Severe		Regardless of	Secondary	Death	Asymptomatic
Based on AC		COVID-19*		Symptomatology	Definition	Caused by	SARS-CoV-2
Assessments	COVID-19*	Assessments	Severe	and Severity	of COVID-19*	COVID-19	Infection
Subject ID: US3942091; Age (Year): 57; Sex: M; Race: WHITE; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 25.8; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Positive; Date of First/Second Injection: 2020-09-11/							
No	No	No	No	Yes/ 2020-10-09 (29)/3	No	No	Yes/ 2020-10-09 (29)/3
Subject ID: US3942153; Age (Year): 45; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Ethnicity: NOT HISPANIC OR LATINO; BMI (kg/m²): 40.9; PP Set: No; Baseline RT-PCR: Positive; Baseline Elecsys: Negative; Date of First/Second Injection: 2020-10-12/2020-11-06							
No	No	No	No	Yes/ 2020-11-06 (26)/4	No	No	Yes/ 2020-11-06 (26)/4

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\11602060205.sas 23JUN2021 06:52

Listing 16.2.6.2.5
Primary and Secondary Efficacy Endpoints
Randomization Set

AC = Adjudication Committee, BMI = body mass index, PP = Per-Protocol, RT-PCR = reverse transcription polymerase chain reaction.

This listing includes subjects who have at least one documented case of the primary and secondary endpoints.

Rel Day is defined as study day from randomization date.

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] 1 = after randomization. 2 = after first injection. 3 = after 14 days following first injection. 4 = after second injection. 5 = after 14 days following second injection. The latest time window is displayed if the first event onset day belongs to multiple windows.