

Listing 16.2.7.18
Unsolicited Adverse Events – Vasculitis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|----------------------------------|--|---|
| Subject ID: US3432023; Age (years): 83; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Musculoskeletal and connective tissue disorders/ Polymyalgia rheumatica/ POSSIBLE POLYMYALGIA RHEUMATICA | 2020-08-20 (16)/ Ongoing | Yes/ Yes/ No | 3 (2020-08-20/ 2020-08-21) | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020718.sas 03DEC2020 06:16

Listing 16.2.7.18
Unsolicited Adverse Events – Vasculitis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|---------|
|--|---|-----------------------------------|-------------------------------|--|---------|

There are no observations for this section.

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020718.sas 03DEC2020 06:16

Listing 16.2.7.18
Unsolicited Adverse Events – Vasculitis
Safety Set

Vasculitis is identified through selected SMQ.

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3002216; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ACE INHIBITOR INDUCED ANGIOEDEMA | 2020-09-11 (12)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3012254; Age (years): 55; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH - LEFT SIDE OF GLUTEUS | 2020-10-30 (26)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3012263; Age (years): 50; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH, BACK AND BUTTOCKS | 2020-11-15 (47) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3022295; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH UNDER LEFT BREAST NON-URTICARIAL | 2020-09-14 (20) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3032171; Age (years): 52; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIA | 2020-09-13 (35) / 2020-09-24 (46) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|---------------------------|---|---|------------------------|
| Subject ID: US3032283; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS RIGHT EAR AND CHEEK | 2020-09-09 (21) / 2020-09-30 (42) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3042252; Age (years): 54; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ BILATERAL HAND RASH | 2020-09-23 (8) / 2020-10-14 (29) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3082038; Age (years): 47; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR RASH [RIGHT UPPERARM] | 2020-08-18 00:00 (1)/ 2020-09-03 07:00 (17) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR RASH (BOTH FOREARMS) (NON-URTICARIAL) | 2020-08-23 (7)/ 2020-09-03 (18) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3092303; Age (years): 67; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH- FACE | 2020-10-20 (15)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash/ RASH-THIGHS | 2020-10-20 (15)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3102340; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES RT ELBOW AND CHEST | 2020-09-27 (17)/ 2020-10-04 (24) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3112362; Age (years): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-19 (27) / 2020-09-19 (27) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3112413; Age (years): 25; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS LEFT ARM | 2020-10-22 (57) / 2020-10-29 (64) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3152210; Age (years): 45; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-08-28 (15) / 2020-09-03 (21) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3152297; Age (years): 23; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Drug hypersensitivity/ ALLERGY TO ABILIFY | 2020-09-02 (16)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO ABILIFY | 2020-09-02 (16)/ 2020-09-08 (22) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3152308; Age (years): 34; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-09-26 (6)/ 2020-10-02 (12) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3152362; Age (years): 31; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ WORSENING ECZEMA MULTIPLE LOCATIONS | 2020-08-23 (3) / 2020-08-30 (10) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3152378; Age (years): 44; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS - POISON IVY | 2020-09-16 (26) / 2020-10-10 (50) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3152394; Age (years): 38; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ WORSENING OF RASH BILATERAL, UPPER EXTREMITIES | 2020-09-27 (26)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3182030; Age (years): 38; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH-RIGHT FOREARM | 2020-08-22 (26)/ 2020-08-26 (30) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3182286; Age (years): 36; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ FACIAL RASH | 2020-11-02 (54) / 2020-11-16 (68) | Yes/ Yes/ No | 1 No | NA/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3192403; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis allergic/ OTIS EXTERNA DERMATITIS, ALLERGIC | 2020-08-29 (9) / 2020-09-10 (21) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3192449; Age (years): 49; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ DRY ITCHY RASH ON RIGHT KNEE AND LEFT ELBOW | 2020-10-30 (40) / 2020-11-20 (61) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3192535; Age (years): 74; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR RASH LEFT THIGH NON URTICARIA | 2020-09-05 (9) / 2020-09-12 (16) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3202039; Age (years): 45; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-08-31 (26) / 2020-09-10 (36) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3202172; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH | 2020-08-17 (5) / 2020-08-27 (15) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3202225; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-11-15 (60) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|-------------------------------|---|--------------------------|
| Subject ID: US3212188; Age (years): 20; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-10-09 (11)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3212210; Age (years): 40; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS - RIGHT JAWLINE | 2020-08-31 (15)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3212276; Age (years): 81; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Eye disorders/ Conjunctivitis allergic/ ACUTE CONJUNCTIVITIS - ALLERGIC | 2020-09-11 (23)/ 2020-09-14 (26) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3222510; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-11-06 (28) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3262224; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-09-21 (33) / 2020-09-21 (33) | Yes/ No/ Yes | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3272184; Age (years): 41; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS (NASAL) | 2020-10-05 (20) / 2020-10-06 (21) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3282080; Age (years): 68; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES TO GLUTEUS MAXIMUS | 2020-09-26 (33) / 2020-09-26 (33) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---|--|--|
| Subject ID: US3292339; Age (years): 70; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA | 2020-09-16 (21) / 2020-09-18 (23) | Yes/ Yes/ No | 4 Yes/2/3 (2020-09-17/ 2020-09-18) | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3292375; Age (years): 54; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON FACE ALL THE WAY TO MID-TORSO | 2020-09-19 (22) / 2020-09-19 (22) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3292383; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BILATERAL FOREARMS | 2020-09-12 (15)/ 2020-09-25 (28) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3302362; Age (years): 50; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLERGIC DERMATITIS | 2020-10-07 (13)/ 2020-10-12 (18) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3312020; Age (years): 73; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS (RIGHT LEG/BILATERAL ARMS) | 2020-08-28 (18) / 2020-09-24 (45) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3312530; Age (years): 53; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-10-24 (20) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|--------------------------------|
| Subject ID: US3322275; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ PRURITIC ERYTHEMATOUS RASH OF LEFT SIDE OF FACE | 2020-09-14 (6) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3342031; Age (years): 22; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS (BILATERAL AXILLARY) | 2020-09-12 (33) / 2020-09-15 (36) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3342077; Age (years): 34; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-11-01 (45) / 2020-11-15 (59) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342079; Age (years): 51; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-25 (40) / 2020-10-26 (41) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3342140; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS | 2020-10-01 (11)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3342187; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-11-02 (18)/ 2020-11-08 (24) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|---------------------------|---|---|--------------------------|
| Subject ID: US3342192; Age (years): 39; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS- POISON IVY | 2020-09-21 (18) / 2020-10-15 (42) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3342200; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS EXACERBATION | 2020-09-04 22:00 (1) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3342201; Age (years): 73; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ ALLERGIC CONTACT DERMATITIS LEFT ARM | 2020-09-04 21:00 (1)/ Ongoing | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3342262; Age (years): 72; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-19 (25)/ 2020-10-24 (30) | Yes/ No/ No | 1 No | NR/ NR | DOSE DELAYED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3342276; Age (years): 47; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-04 (12)/ 2020-10-06 (14) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342328; Age (years): 37; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ ALLERGEN | 2020-11-23 (8)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3352099; Age (years): 30; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Palatal oedema/ UVULA EDEMA | 2020-10-13 (27)/ 2020-10-18 (32) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3362006; Age (years): 60; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ WORSENING OF ATOPIC DERMATITIS | 2020-10-26 (59) / Ongoing | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3362009; Age (years): 35; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Allergic sinusitis/ ALLERGIC RHINOSINUSITIS | 2020-08-02 (2) / 2020-08-05 (5) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3362027; Age (years): 35; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ IRRITATED CONTACT DERMATITIS LEFT ARM (INJECTION SITE BANDAID) | 2020-09-02 (2)/ 2020-09-02 (2) | Yes/ No/ No | 1 No | NR/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3362096; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-02 (15)/ 2020-10-14 (27) | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3362118; Age (years): 52; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS (POISON IVY) | 2020-09-22 (9) / 2020-10-04 (21) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ DERMATITIS (POISON IVY) BOTH ARMS AND RIGHT LEG | 2020-09-22 (9) / 2020-10-04 (21) | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3372152; Age (years): 81; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ DERMAL RASH ABDOMEN RIGHT UPPER QUADRANT | 2020-09-01 (15)/ Ongoing | Yes/ No/ Yes | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3372193; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ RASH FROM SLING IN THE LEFT ARM-MACULAR NON-URTICARIAL | 2020-09-19 (31)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3382042; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS OF THE FACE | 2020-09-30 (17)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3382085; Age (years): 41; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLERGIC RASH - UNKNOWN ETIOLOGY | 2020-09-12 (24)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|--------------------------|
| Subject ID: US3412024; Age (years): 19; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ PERINASAL DERMATITIS - NOSE AND FACE. | 2020-08-03 (6)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3412074; Age (years): 51; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ RASH, BILATERAL LOWER EXTREMITIES (MACULOPAPULAR) (NON-URTICARIAL) | 2020-08-11 (12)/ 2020-08-12 (13) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3412276; Age (years): 25; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ ALLERGIC REACTION- MILD TO LAUNDRY DETERGENT | 2020-09-13 (27)/ 2020-09-13 (27) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3412319; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL - RASH - BILATERAL FOREARMS | 2020-09-16 (23)/ 2020-09-19 (26) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3422087; Age (years): 57; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS/POISON IVY | 2020-10-08 (18) / 2020-10-12 (22) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3432198; Age (years): 31; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH (MOUTH AND CHIN) | 2020-09-17 (2) / 2020-09-19 (4) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3432295; Age (years): 83; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis bullous/ DIFFUSE BULLOUS RASH (NON-URTICARIAL) | 2020-09-12 (18) / 2020-10-02 (38) | Yes/ Yes/ No | 4 | Yes/1/3 (2020-09-17/ 2020-09-24) | NR/ NR DOSE DELAYED/ CONCOMITANT MEDICATION FATAL |
| Subject ID: US3432444; Age (years): 31; Sex: F; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH (LEGS AND ABDOMEN) | 2020-09-22 (19) / 2020-09-23 (20) | Yes/ No/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3442121; Age (years): 35; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON NECK | 2020-10-22 (21) / 2020-10-25 (24) | Yes/ Yes/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|--|-----------------------------------|---|-------------------------------|---|------------------------|
| Subject ID: US3442217; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-14 (9) / 2020-11-19 (45) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3462111; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Laryngeal oedema/ LARYNGEAL EDEMA | 2020-09-19 (5) / 2020-09-24 (10) | Yes/ Yes/ No | 4 Yes/3 (2020-09-19/ 2020-09-20) | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3472041; Age (years): 49; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS | 2020-09-24 (11) / 2020-10-08 (25) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3472057; Age (years): 52; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-09-19 (3)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3472118; Age (years): 28; Sex: M; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS - BILATERAL ANTERIOR LEGS, BILATERAL WRISTS, CHEST | 2020-11-02 (15)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3482052; Age (years): 52; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Injury, poisoning and procedural complications/ Injection related reaction/ SOLICITED LOCAL OR SYSTEMIC AR LASTING BEYOND 7 DAYS POST INJECTION. REPORTED HEADACHES, FATIGUE, MUSCLE ACHES, AND JOINT ACHES. | 2020-09-08 (1)/ 2020-09-18 (11) | Yes/ Yes/ Yes | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3482086; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL UPPER CHEST RASH | 2020-09-22 (7) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3482087; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY | 2020-09-07 (20) / 2020-09-13 (26) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3492014; Age (years): 64; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS LEFT THIGH | 2020-11-04 (43) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3502216; Age (years): 39; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Anaphylactic reaction/ ANAPHYLAXIS | 2020-11-02 (11) / 2020-11-02 (11) | Yes/ Yes/ No | 3 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3512009; Age (years): 78; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO CEPHALEXIN CAUSING EDEMATOUS NON- URTICARIAL LIPS | 2020-08-28 (24) / 2020-09-11 (38) | Yes/ No/ No | 2 No | NR/ NR | DOSE DELAYED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3512009; Age (years): 78; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Gastrointestinal disorders/ Lip swelling/ ALLERGIC REACTION OF INTERMITTENT LIP SWELLING | 2020-09-17 (2)/ Ongoing | Yes/ Yes/ Yes | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3512065; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis bullous/ BULLOUS RASH IN RIGHT AXILLARY REGION IPILATERAL TO INJECTION SITE NON-URTICARIAL | 2020-08-14 12:00 (1)/ 2020-08-15 08:00 (2) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE AND NECK | 2020-08-31 (3)/ Ongoing | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK) | 2020-08-31 (3)/ 2020-10-04 (37) | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK) | 2020-10-08 (41) / Ongoing | Yes/ No/ No | 1 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3512214; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ LOCALIZED ALLERGIC REACTION TO DEODORANT | 2020-10-05 (4) / 2020-10-09 (8) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3522045; Age (years): 32; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ CHRONIC ECZEMA FLARE-UP | 2020-10-07 (34)/ Ongoing | Yes/ No/ Yes | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3522233; Age (years): 21; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ URTICARIAL, PAPULAR RASH, UNKNOWN ETIOLOGY | 2020-10-07 (16)/ 2020-10-25 (34) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3522467; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE/NECK | 2020-09-18 (19)/ Ongoing | Yes/ No/ No | 1 No | R/ NA | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3522509; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS OF TRUNK AREA; ABD AND BACK | 2020-11-19 (49)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3532031; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Periorbital oedema/ BILATERAL PERIORBITAL EDEMA | 2020-09-04 (22)/ 2020-09-05 (23) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3532114; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PRURITIC PAPULES- BILATERAL ARMS AND LEGS, ABDOMEN | 2020-08-23 (3)/ 2020-10-27 (68) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3532117; Age (years): 47; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH ON ARMS AND LEGS, URTICARIAL | 2020-09-19 (27)/ 2020-10-13 (51) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3532276; Age (years): 77; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ RHINITIS- ALLERGIC | 2020-10-20 (13)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3542231; Age (years): 69; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH ON FACE | 2020-10-10 (26) / 2020-10-26 (42) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3542321; Age (years): 44; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ BACK OF NECK MACULOPAPULAR RASH | 2020-11-03 (29) / 2020-11-03 (29) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3552111; Age (years): 66; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY (BILATERAL ARMS) | 2020-09-10 (22)/ 2020-09-13 (25) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3552163; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash follicular/ PAPULAR FOLLICULAR RASH - NECK, CHEST AND TRUNK | 2020-09-20 (27)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3552163; Age (years): 57; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash follicular/ PAPULAR, FOLLICULAR RASH - SPREAD TO LEFT BREAST AND LEFT SIDE OF NECK | 2020-10-14 (23)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3552303; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL MACULAR PAPULAR RASH ON RIGHT ARM | 2020-09-13 (12)/ 2020-09-17 (16) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3552399; Age (years): 58; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-10-08 18:00 (1)/ 2020-11-09 (33) | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3552505; Age (years): 23; Sex: F; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH TO FACE, JAW, LIPS | 2020-11-06 (12)/ 2020-11-18 (24) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3552530; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIAL RASH | 2020-10-18 (5) / 2020-11-13 (31) | Yes/ Yes/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3562097; Age (years): 30; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH UNDER INJECTION SITE | 2020-10-02 (2) / 2020-10-03 (3) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3562097; Age (years): 30; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH ELBOW AREA INJECTION ARM | 2020-10-05 (5)/ 2020-10-08 (8) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3572167; Age (years): 43; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON BOTH LEGS - ON CALF AND SHINS BILATERAL | 2020-10-20 (20)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3582154; Age (years): 29; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA | 2020-09-23 (6) / 2020-09-26 (9) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3592027; Age (years): 54; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS, GENERALIZED | 2020-11-11 (52) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ SWELLING TO THE RIGHT SIDE OF THE FACE | 2020-09-17 (7)/ 2020-09-27 (17) | Yes/ Yes/ No | 2 Yes/6 | R/ NR | DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3602034; Age (years): 38; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ BILATERAL EYELID PUFFINESS | 2020-10-27 (19)/ 2020-10-29 (21) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|--|
| Subject ID: US3602034; Age (years): 38; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ BILATERAL EYELID SWELLING | 2020-10-27 (19) / 2020-10-29 (21) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3602084; Age (years): 42; Sex: M; Race: OTHER: NOT SPECIFIED BY SUBJECT; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ SWELLING ON LEFT SIDE OF CHEEK | 2020-10-08 (17) / 2020-10-17 (26) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3602084; Age (years): 42; Sex: M; Race: OTHER: NOT SPECIFIED BY SUBJECT; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ BILATERAL HAND RASH-- DORSUM WITH HIVES | 2020-11-03 (14) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Eye disorders/ Periorbital swelling/ BILATERAL PUFFY EYES | 2020-11-03 (14) / 2020-11-04 (15) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3622191; Age (years): 20; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Gingival swelling/ LEFT LOWER JAW GUM SWELLING/PUS (BEHIND WISDOM TOOTH) | 2020-10-27 (14) / 2020-11-11 (29) | Yes/ Yes/ No | 1 No | NR/ NR | NOT RECOVERED/ RESOLVED APPLICABLE/ CONCOMITANT MEDICATION |
| Subject ID: US3662019; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Periorbital swelling/ PERI-ORBITAL SWELLING | 2020-09-10 (15) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3662071; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ UNDERARM RASH | 2020-10-15 (4) / 2020-10-29 (18) | Yes/ Yes/ No | 2 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3662072; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ ITCHING AT MACULAR RASH SITE, LEFT SIDE OF CHEST WALL, | 2020-09-23 (14)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR RASH, SKIN, LEFT SIDE OF CHEST WALL | 2020-09-23 (14)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3662083; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ ITCHING RASH AREA-SKIN (SEE LOG LINE 1) | 2020-09-29 (19) / 2020-09-30 (20) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH DISSEMINATED-URTICARIA | 2020-09-29 (19) / 2020-09-30 (20) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3672038; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS ON LEFT AND RIGHT FOREARMS AND RIGHT BICEP | 2020-08-17 (8)/ 2020-09-03 (25) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3672151; Age (years): 25; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ PRUITIC RASH LOWER EXTREMITIES | 2020-08-18 12:15 (1)/ 2020-08-26 (10) | Yes/ Yes/ No | 2 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3672306; Age (years): 58; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ LOCALIZED SKIN RASH RIGHT UPPER CHEST | 2020-09-18 (24)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3682138; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ WELTS - ITCHY - ABODEMNI AND ARMS | 2020-10-24 (13)/ 2020-10-28 (17) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3682165; Age (years): 51; Sex: M; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO OXYCONTIN | 2020-10-19 (25)/ 2020-10-19 (25) | Yes/ No/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3692093; Age (years): 36; Sex: F; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON FACE | 2020-10-11 (4)/ Ongoing | Yes/ No/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON JAWS | 2020-10-11 (4)/ Ongoing | Yes/ No/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3692093; Age (years): 36; Sex: F; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON SHOULDERS | 2020-10-11 (4)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3702044; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Drug hypersensitivity/ MACROBID ALLERGIC REACTION | 2020-11-09 (19)/ Ongoing | Yes/ Yes/ No | 3 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3712086; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA RASH (HIVES) (ANTERIOR UPPER AND LOWER ARM) | 2020-09-16 02:00 (1)/ 2020-09-25 18:00 (11) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3722107; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY | 2020-08-19 (15)/ 2020-10-05 (62) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3722133; Age (years): 54; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH BILATERAL UPPER ARMS AND CHEST | 2020-10-09 (32)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3732088; Age (years): 54; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ RHINITIS, ALLERGIC | 2020-09-20 (6)/ 2020-09-29 (15) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3732090; Age (years): 78; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ EXACERBATION OF ALLERGIC RHINITIS | 2020-10-12 (28) / 2020-10-17 (33) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3732140; Age (years): 55; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ WORSENING ENVIRONMENTAL ALLERGIES | 2020-10-05 (12) / 2020-10-08 (15) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3732176; Age (years): 85; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS, BILATERAL LOWER EXTREMITIES | 2020-08-31 (6) / 2020-10-23 (59) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3732210; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ RIGHT FOOT DERMATITIS | 2020-09-27 (31) / Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3732248; Age (years): 27; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS NOT OTHERWISE SPECIFIED | 2020-10-04 (6) / 2020-10-09 (11) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3732285; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-02 (1) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3732285; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON RIGHT FOREARM | 2020-10-29 (28) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3732339; Age (years): 37; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASHES ALL OVER BODY (EXCEPT FACE AND NECK) | 2020-10-06 (22) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3732376; Age (years): 50; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH, FACIAL | 2020-10-10 (16) / 2020-10-18 (24) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3742123; Age (years): 36; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BILATERAL ARMS | 2020-10-05 (33) / 2020-10-09 (37) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3742325; Age (years): 35; Sex: M; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ BILATERAL RASH UNDERARM | 2020-10-23 (5) / 2020-10-31 (13) | Yes/ No/ Yes | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3742341; Age (years): 50; Sex: M; Race: NOT REPORTED; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH | 2020-09-12 05:00 (1) / Ongoing | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3742363; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Serum sickness/ SERUM SICKNESS | 2020-09-22 (6) / Ongoing | Yes/ Yes/ No | 2 No | R/ NR | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3752039; Age (years): 37; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ UNSPECIFIED CONTACT DERMATITIS DUE TO PLANT [POISON IVY] | 2020-08-25 (15) / 2020-09-15 (36) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3752250; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Lip swelling/ LIP SWELLING | 2020-09-12 (19) / 2020-09-19 (26) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|--|-----------------------------------|-------------------------------|--|--------------------------|
| Subject ID: US3752295; Age (years): 35; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON ARMS AND LEGS (TYPE OF RASH OR IF URTICARIAL OR NONURTICARIAL UNKNOWN) | 2020-09-12 (16) / 2020-09-24 (28) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES ON LEGS, ARMS, BACK, AND TORSO | 2020-09-20 (24) / Ongoing | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3782073; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA | 2020-08-28 (5)/ Ongoing | Yes/ Yes/ No | 3 No | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3782168; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ RED, MILDLY PRURITIC, FLAKY, NON-URTICARIAL MALAR RASH | 2020-11-18 (37)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|--|-----------------------------------|-------------------------------|--|---------------------------------------|------------------------|
| Subject ID: US3802023; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ MACULAR GENERALIZED BILATERAL LEGS URTICARIAL RASH | 2020-09-19 (27) / 2020-10-06 (44) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3802233; Age (years): 41; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ UNSPECIFIED ALLERGIC REACTION, MILD, AND WITHOUT SIGNIFICANT SOFT TISSUE SWELLING OR AIRWAY COMPROMISE - SWOLLEN EARS, TINGLING TONGUE AND LIPS | 2020-10-15 (4)/ 2020-10-28 (17) | Yes/ Yes/ No | 2 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3812015; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ WORSENING ALLERGIES | 2020-10-05 (36)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3812044; Age (years): 60; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIA ON BACK AND BLE (DUE TO TICK BITES) | 2020-08-23 (19)/ 2020-10-07 (64) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3812346; Age (years): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS OF LOW BACK | 2020-10-11 (10)/ 2020-11-05 (35) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3822006; Age (years): 51; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Eye disorders/ Eye swelling/ SWELLING UNDER EYE, BILATERAL | 2020-08-09 (6)/ Ongoing | Yes/ Yes/ No | 1 No | R/ R | DRUG WITHDRAWN/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3822011; Age (years): 42; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ FACIAL RASH, UNKNOWN TYPE | 2020-08-14 (10)/ Ongoing | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3822017; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH, BILATERAL ARMS AND ANKLES | 2020-09-04 (5) / 2020-09-10 (11) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3822057; Age (years): 41; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH | 2020-08-13 (4) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|--------------------------|
| Subject ID: US3822118; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH, GENERALIZED | 2020-10-02 (23)/ Ongoing | Yes/ No/ No | 3 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3822379; Age (years): 37; Sex: M; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ NONURTICARIAL RASH ON FOREHEAD AND CHEEKS - SOC: SKIN AND SUBCUTANEOUS TISSUE DISORDERS HLGT: EPIDERMAL AND DERMAL CONDITIONS HLT: RASHES, ERUPTIONS AND EXANTHEMS NEC PT: RASH LLT: RASH ON FACE | 2020-09-22 00:00 (14)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3832087; Age (years): 68; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY DERMATITIS | 2020-09-18 (18)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3862137; Age (years): 82; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA RASH | 2020-10-29 (24)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3872031; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ ECZEMA AGGRAVATED | 2020-09-23 (23)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|--|-----------------------------------|---------------------------|--|---|------------------------|
| Subject ID: US3872095; Age (years): 68; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON ARMS | 2020-10-17 (44) / 2020-10-17 (44) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3872253; Age (years): 30; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ RASH (ALL OVER BODY), RED PATCHES | 2020-09-12 00:00 (22) / 2020-09-24 (35) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3892032; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Eye disorders/ Conjunctivitis allergic/ ALLERGIC CONJUNCTIVITIS | 2020-09-27 (28) / 2020-09-28 (29) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3892032; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON MID BACK (URTICARIA) | 2020-11-12 (46)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION |
| Subject ID: US3902019; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BUTTOCKS AND BILATERAL AXILLA | 2020-09-05 (4)/ Ongoing | Yes/ No/ No | 2 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3902064; Age (years): 50; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Eye swelling/ SWOLLEN RIGHT EYE | 2020-09-18 (9) / 2020-09-25 (16) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3912020; Age (years): 57; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH (BOTH ARMS AND ABDOMEN) | 2020-11-16 (53) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3912151; Age (years): 29; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ BILATERAL UNDERARM RASH | 2020-10-14 (6) / 2020-11-08 (31) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3922117; Age (years): 22; Sex: M; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ WORSENING OF ECZEMA | 2020-11-05 (22)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3942042; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ RASH TO ADHESIVE ON LEFT ARM | 2020-09-01 16:00 (1)/ 2020-09-05 22:00 (5) | Yes/ No/ No | 1 No | NR/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3962004; Age (years): 46; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY | 2020-11-05 (52)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3982143; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ SKIN RASH ON (L) SIDE OF NECK (URTICARIAL AND PAPULAR) | 2020-09-10 06:00 (1)/ 2020-09-13 06:00 (4) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3982275; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Idiopathic urticaria/ IDIOPATHIC URTICARIA | 2020-10-21 (8)/ 2020-10-21 (8) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3002027; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR RASH ON NECK (NON-URTICARIAL) | 2020-09-05 (11)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT NOT RECOVERED/ NOT RESOLVED APPLICABLE/ CONCOMITANT MEDICATION |
| Subject ID: US3002155; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ URTICARIA AT INJECTION SITE | 2020-08-14 (3)/ 2020-09-04 (24) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3002155; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ URTICARIA AT INJECTION SITE | 2020-09-11 (3)/ 2020-09-13 (5) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3012246; Age (years): 21; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES (ALL OVER BODY) | 2020-10-25 (28)/ 2020-10-25 (28) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|------------------------|
| Subject ID: US3022193; Age (years): 70; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS | 2020-10-06 (20)/ 2020-10-13 (27) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3022252; Age (years): 77; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO HIBICLENS ANTISEPTIC | 2020-09-25 (8)/ 2020-09-26 (9) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3032280; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Immune system disorders/ Hypersensitivity/ ENVIRONMENTAL ALLERGIES | 2020-09-07 (19)/ 2020-09-08 (20) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|--------------------------|
| Subject ID: US3042151; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Infections and infestations/ Rash pustular/ RASH ON TORSO-PUSTULAR; NON-URTICARIAL | 2020-10-05 (20)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NA NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3062042; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ NON- URTICARIAL POISON IVY, RASH GENERALIZED | 2020-08-04 08:00 (1)/ 2020-08-09 08:00 (6) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|------------------------|
| Subject ID: US3082081; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-01 (11)/ 2020-10-05 (15) | Yes/ No/ No | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3082101; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO METRONIDAZOLE | 2020-11-12 (52)/ 2020-11-14 (54) | Yes/ Yes/ No | 2 No | NA/ NA | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3082140; Age (years): 67; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ RASH R/T ALLERGY OF LAUNDRY DETERGENT (NON-URTICARIAL) | 2020-09-14 (18)/ 2020-09-20 (24) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3082184; Age (years): 28; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ LEFT ARM URTICARIAL REDNESS AROUND INJECTION SITE | 2020-09-10 (9)/ 2020-09-15 (14) | Yes/ No/ No | 1 No | NR/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3102179; Age (years): 19; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH | 2020-08-19 (9) / 2020-09-21 (42) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3112046; Age (years): 45; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH LOWER BACK-NON-URTICARIAL | 2020-08-28 20:00 (1) / 2020-09-03 (7) | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3112206; Age (years): 75; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS LEFT ARM | 2020-08-20 (9) / 2020-09-07 (27) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3112237; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ WELT AT L DELTOID INJECTION SITE | 2020-08-21 (9) / 2020-08-22 (10) | Yes/ No/ No | 1 No | NR/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3112343; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Conjunctivitis allergic/ ALLERGIC CONJUNCTIVITIS | 2020-08-22 03:00 (1)/ 2020-08-28 (8) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3122047; Age (years): 28; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HYPERSENSITIVITY RASH - BILATERAL ELBOWS (MACULAR - URTICARIAL) | 2020-08-04 (9)/ 2020-08-11 (16) | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|-------------------------------|---|--------------------------------|
| Subject ID: US3152120; Age (years): 32; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH | 2020-08-21 (15)/ 2020-09-11 (36) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3152375; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ WORSENING OF ATOPIC DERMATITIS | 2020-10-01 (11)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3152459; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash vesicular/ HERPETIC RASH GROIN | 2020-10-27 (20)/ 2020-11-15 (39) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3162007; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA TRUNK | 2020-08-06 (11)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3162033; Age (years): 34; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ URTICARIA AT INJECTION SITE | 2020-08-07 (9)/ 2020-08-10 (12) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3162033; Age (years): 34; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULOPAPULAR AND URTICARIAL, RIGHT ARM | 2020-08-27 07:30 (28)/ 2020-09-11 (44) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3162069; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE AFTER DAY 7, MACULOPAPULAR AND URTICARIAL | 2020-09-05 07:00 (1)/ 2020-09-14 07:00 (10) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3162086; Age (years): 55; Sex: F; Race: NOT REPORTED; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ DELAYED INJECTION SITE RASH, PAPULAR AND URTICARIAL | 2020-08-25 (19)/ 2020-08-26 (20) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3162117; Age (years): 26; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ REDNESS OF INJECTION SITE PAST DAY 7, MACULAR AND URTICARIAL | 2020-08-14 (2)/ 2020-08-24 (12) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3162118; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ REDNESS AT INJECTION SITE BEYOND DAY 7, MACULAR, URTICARIAL | 2020-09-14 22:30 (1)/ 2020-09-29 (16) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3162253; Age (years): 55; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE STARTING AFTER DAY 7, MACULAR, URTICARIAL, LEFT ARM | 2020-10-06 (14)/ Ongoing | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3172265; Age (years): 34; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ SKIN RASH (CONSISTENT WITH HIVES) (ARMS, LEGS, CHEST, AND BACK) | 2020-08-22 23:00 (2)/ 2020-08-25 05:00 (4) | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|--|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3172343; Age (years): 50; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RIGHT DELTOID REDNESS ON THE INJECTION SITE (MACULOPAPULAR AND NON-URTICARIAL) | 2020-09-03 (9) / 2020-09-05 (11) | Yes/ No/ Yes | 1 No | R/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3182290; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ SKIN RASH-ABDOMEN /LOWER BACK | 2020-09-11 19:00 (2) / 2020-09-12 08:00 (2) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3192022; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON BILATERAL HANDS AND EXTREMITIES | 2020-08-11 (10)/ 2020-08-17 (16) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3192245; Age (years): 77; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA ON LEFT SIDE OF BODY INCLUDING ARM, LEG AND SOMETIMES LOWER ABDOMEN | 2020-10-16 (36)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3212091; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH | 2020-08-15 (9) / 2020-08-18 (12) | Yes/ No/ No | 1 No | R/ R | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3212204; Age (years): 54; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ FACIAL ECZEMA EXACERBATION | 2020-08-31 (15) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3212316; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA OF THE STOMACH, BREASTS AND BILATERAL NECK. | 2020-09-24 (3)/ 2020-09-26 (5) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3222316; Age (years): 79; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Type IV hypersensitivity reaction/ DELAYED TYPE-HYPERSENSITIVITY | 2020-08-31 (8)/ 2020-09-04 (12) | Yes/ Yes/ Yes | 3 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|--------------------------|
| Subject ID: US3242126; Age (years): 36; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS, RIGHT FOREARM | 2020-10-05 (21)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3262133; Age (years): 58; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Anaphylactic reaction/ ANAPHYLAXIS | 2020-11-07 08:30 (63)/ 2020-11-07 08:45 (63) | Yes/ Yes/ Yes | 2 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|--|
| Subject ID: US3272162; Age (years): 46; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-02 (15) / 2020-10-05 (18) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3292059; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIA | 2020-09-18 (14) / 2020-10-01 (27) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3292156; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ NON-URTICARIAL RASH ON LEFT HAND AND ARM | 2020-08-18 (6) / 2020-08-18 (6) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3292180; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON ARM | 2020-09-16 (2) / 2020-09-23 (9) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3292241; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Eye swelling/ LEFT EYE SWELLING | 2020-08-21 (2) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3292276; Age (years): 39; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-08-29 (9) / Ongoing | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3292279; Age (years): 51; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-11-12 (55) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3292393; Age (years): 60; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON NOSE | 2020-09-22 (8) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|--------------------------|
| Subject ID: US3302200; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS | 2020-08-14 (2)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERING/ RESOLVING |
| Subject ID: US3312014; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED RAISED, URTICARIAL, ERYTHEMATOUS RASH (ON CHEST, STOMACH, PROXIMAL UPPER AND LOWER EXTREMITIES) | 2020-09-08 (2)/ 2020-09-10 (4) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3312021; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Drug hypersensitivity/ ALLERGIC REACTION TO BACTRIM | 2020-10-05 (29) / 2020-10-09 (33) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3312109; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ LEFT INJECTION SITE RASH (NON-URTICARIAL) | 2020-08-25 (9) / 2020-08-29 (13) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3312120; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE (LEFT) MACULOPAPULAR NON-URTICARIAL RASH | 2020-08-25 (8)/ 2020-08-28 (11) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3312188; Age (years): 78; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ MACULAR URTICARIAL RASH AT INJECTION SITE (LEFT ARM) | 2020-08-28 (9)/ 2020-09-26 (38) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3312219; Age (years): 67; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ NON-UTICARIAL MACULAR RASH AT INJECTION SITE (RIGHT ARM) | 2020-08-28 (8)/ 2020-08-31 (11) | Yes/ No/ No | 1 No | R/ R DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3312221; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ URTICARIAL RASH AT INJECTION SITE (LEFT ARM) | 2020-08-28 (8)/ 2020-09-13 (24) | Yes/ No/ No | 1 No | R/ R DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3312242; Age (years): 59; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ EXACERBATION OF ECZEMA | 2020-09-25 (8)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3312249; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ LEFT INJECTION SITE RASH | 2020-09-01 (9)/ 2020-09-04 (12) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3312350; Age (years): 20; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH LEFT ARM | 2020-09-03 (8)/ 2020-09-06 (11) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3312367; Age (years): 58; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE (LEFT) MACULAR NON-UTICAIRAL RASH | 2020-09-04 (8)/ 2020-09-07 (11) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3312367; Age (years): 58; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH | 2020-09-28 (4)/ 2020-10-04 (10) | Yes/ Yes/ Yes | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3312411; Age (years): 58; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH | 2020-10-01 (4)/ 2020-10-17 (20) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3312428; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ LEFT ARM URTICARIAL INJECTION SITE RASH | 2020-09-09 (9)/ 2020-09-09 (9) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3312432; Age (years): 79; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ INJECTION SITE RASH (MACULAR URTICARIAL) | 2020-09-09 (9)/ 2020-09-12 (12) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3312448; Age (years): 40; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ PRURITIC INJECTION SITE RASH | 2020-09-09 (8)/ 2020-09-15 (14) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3312634; Age (years): 36; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ IPSILATERAL INJECTION SITE MACULAR URTICARIAL RASH | 2020-09-18 (8)/ 2020-09-23 (13) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3312639; Age (years): 37; Sex: F; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE (LEFT ARM) MACULOPAPULAR KERATINIZED RASH | 2020-09-21 (11)/ 2020-09-27 (17) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE (LEFT ARM) MACULAR RASH | 2020-10-16 (4)/ 2020-10-19 (7) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|------------------------|
| Subject ID: US3322219; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-04 (2)/ 2020-09-06 (4) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3322308; Age (years): 28; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| General disorders and administration site conditions/ Injection site rash/ DELAYED SITE INJECTION REACTION (RASH) OF LEFT UPPER EXTREMITY | 2020-09-20 (9)/ 2020-09-22 (11) | Yes/ Yes/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING | 2020-10-17 (3)/ 2020-10-22 (8) | Yes/ Yes/ No | 3 Yes/6 | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342009; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ RHINITIS ALLERGENIC | 2020-09-21 (12)/ 2020-09-22 (13) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3342029; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS NECK, UPPER BACK, LEFT ABDOMEN | 2020-10-01 (23)/ 2020-10-15 (37) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342086; Age (years): 21; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis allergic/ BILATERAL EYELID ALLERGIC DERMATITIS | 2020-08-22 (6)/ 2020-08-23 (7) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3342094; Age (years): 35; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-28 (42)/ 2020-10-30 (44) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342099; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Conjunctivitis allergic/ ALLERGIC CONJUNCTIVITIS LEFT EYE | 2020-09-19 (33)/ 2020-09-23 (37) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342203; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS | 2020-11-01 (21)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3342255; Age (years): 36; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-01 (21)/ 2020-10-02 (22) | Yes/ Yes/ No | 1 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3342279; Age (years): 30; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-10-26 (4)/ 2020-11-04 (13) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---|--|---|
| Subject ID: US3342346; Age (years): 58; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-11-03 (22)/ 2020-11-03 (22) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash vesicular/ DISSEMINATED VESICULAR RASH ALL OVER BODY | 2020-11-08 (41)/ 2020-11-13 (46) | Yes/ Yes/ No | 4 Yes/3 (2020-11-08/ 2020-11-13) | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---|--|---|
| Subject ID: US3352299; Age (years): 48; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH SKIN ERUPTION | 2020-11-11 (44)/ Ongoing | Yes/ Yes/ No | 3 Yes/3 (2020-11-11/ 2020-11-13) | NR/ NR | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3352374; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ BILATERAL ELBOW RASH | 2020-09-29 (20)/ 2020-10-04 (25) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3362003; Age (years): 33; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Allergic sinusitis/ WORSENING OF ALLERGIC RHINOSINUSITIS | 2020-08-10 (10)/ 2020-08-18 (18) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3362023; Age (years): 55; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Swollen tongue/ TONGUE SWELLING - POST INJECTION ALLERGIC REACTION | 2020-08-03 16:20 (1)/ 2020-08-03 18:20 (1) | Yes/ Yes/ No | 2 No | R/ NR | DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3362097; Age (years): 53; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ INJECTION SITE RASH RIGHT AXILLA(URTICARIAL) | 2020-08-19 (10)/ 2020-08-28 (19) | Yes/ No/ No | 1 No | R/ R DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3362148; Age (years): 21; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-08-19 (5)/ 2020-09-02 (19) | Yes/ No/ No | 2 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-09-11 (19) / 2020-09-18 (26) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3362280; Age (years): 57; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL RASH TO BACK | 2020-09-14 (6) / 2020-09-16 (8) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3362280; Age (years): 57; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL RASH TO GROIN | 2020-10-09 (3)/ 2020-10-23 (17) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3362308; Age (years): 61; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ LEFT ARM RASH | 2020-10-19 (12)/ 2020-10-24 (17) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3372210; Age (years): 69; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-09-20 (31)/ 2020-09-23 (34) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3372217; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ REDNESS AT THE INJECTION SITE-MACULAR, NON-URTICAR IAL. | 2020-09-01 (9)/ 2020-09-07 (15) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3382036; Age (years): 32; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY DERMATITIS- LEFT LEG | 2020-09-23 (13)/ 2020-09-28 (18) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3382095; Age (years): 42; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ ERYTHEMATOUS RASH OF NECK AND FACE | 2020-09-07 (15)/ 2020-09-10 (18) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|---------------------------------------|--------------------------------|
| Subject ID: US3382147; Age (years): 58; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Exfoliative rash/ URTICARIAL SCALY RASH ON RIGHT FOOT AND ANKLE | 2020-10-15 (18)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERING/ RESOLVING |
| Subject ID: US3382168; Age (years): 25; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH-ITCHY, NEAR INJECTION SITE, UNDER LEFT ARM AND LEFT BREAST AREA | 2020-10-09 (10)/ Ongoing | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3382267; Age (years): 49; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH OVER THE INJECTION SITE | 2020-09-25 (14)/ 2020-09-26 (15) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash/ GENERALIZED RASH | 2020-10-13 (2)/ Ongoing | Yes/ Yes/ No | 3 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3382285; Age (years): 56; Sex: F; Race: MULTIPLE: (b) (6) ; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ URTICARIAL MACULOPAPULAR RASH LEFT ARM | 2020-09-17 08:30 (1)/ 2020-09-18 09:00 (2) | Yes/ No/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ URTICARIAL MACULOPAPULAR RASH LEFT ARM | 2020-09-23 (8)/ 2020-09-24 (9) | Yes/ No/ No | 1 | No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3382293; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH OVER THE LEFT SIDE OF ABDOMEN | 2020-10-02 (15)/ 2020-10-04 (17) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: HYPERPIGMENTAT ION |
| General disorders and administration site conditions/ Injection site rash/ RASH OVER THE INJECTION SITE | 2020-10-03 (16)/ 2020-10-04 (17) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3402360; Age (years): 38; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Hand dermatitis/ LEFT INDEX FINGER DERMATITIS | 2020-09-11 (28)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3412058; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH LEFT ARM | 2020-09-10 (14)/ 2020-09-14 (18) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|------------------------|
| Subject ID: US3412167; Age (years): 37; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS DUE POISON IVY - SMALL AREA ON FOREHEAD. | 2020-10-04 (25)/ 2020-10-12 (33) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3422012; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR RASH BOTH ARMS (NONURTICARIAL) | 2020-08-17 (5)/ 2020-08-31 (19) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3422023; Age (years): 45; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIAL MACULOPAPULAR RASH ON CHEST | 2020-09-18 (4) / 2020-09-20 (6) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3422127; Age (years): 40; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NONURTICARIAL MACULOPAPULAR RASH AT L DELTOID | 2020-09-26 (3) / 2020-10-02 (9) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3422142; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ URTICARIAL REDNESS AT L DELTOID INJECTION SITE 13 DAYS POST VACCINE | 2020-09-09 (13)/ 2020-09-23 (27) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| General disorders and administration site conditions/ Injection site urticaria/ URTICARIAL REDNESS AT L DELTOID INJECTION SITE | 2020-09-26 14:00 (2)/ 2020-10-07 (13) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3422187; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ NON-URTICARIA MACULOPAPULAR AT INJECTION SITE 9 DAYS POST VACCINE | 2020-09-10 (9) / 2020-09-16 (15) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3422202; Age (years): 27; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIA MACULOPAPULAR OF LEFT DELTOID 9 DAYS POST VACCINATION | 2020-09-11 (9) / 2020-09-17 (15) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3432014; Age (years): 58; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH (LOWER LEFT ARM) | 2020-09-11 (10) / 2020-09-19 (18) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3432119; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA LOCALIZED ON NECK AND CHEEK | 2020-09-15 (2) / 2020-09-16 (3) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3432192; Age (years): 49; Sex: M; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-09-02 (6) / 2020-09-02 (6) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3432203; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH (R ARM, L HIP) | 2020-09-23 (8) / 2020-10-14 (29) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|-------------------------------|---|--------------------------------|
| Subject ID: US3432341; Age (years): 33; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ EXANTHEM ON RIGHT HAND | 2020-10-21 (27)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3432421; Age (years): 67; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Bronchospasm/ BRONCHOSPASM | 2020-09-24 (22)/ 2020-10-12 (40) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3432465; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH | 2020-10-22 (17)/ 2020-10-22 (17) | Yes/ Yes/ No | 2 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3432465; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC RASH | 2020-10-26 (21)/ 2020-10-26 (21) | Yes/ Yes/ No | 2 No | R/ R | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3442178; Age (years): 39; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH UPPER BODY: NON-URTICARIAL | 2020-09-18 (3)/ 2020-09-20 (5) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3442178; Age (years): 39; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH UPPER EXTREMITIES: NON-URTICARIAL | 2020-09-18 (3) / 2020-09-20 (5) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash/ RASH UPPER BODY: NON-URTICARIAL | 2020-10-16 (2) / 2020-10-17 (3) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3442230; Age (years): 59; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-11-06 (25)/ 2020-11-09 (28) | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3472048; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ NON URTICARIAL RASH - MIDDLE OF BACK | 2020-09-22 (7)/ 2020-10-07 (22) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3472048; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ NON URTICARIAL RASH - MIDDLE OF BACK | 2020-10-16 (3)/ Ongoing | Yes/ No/ No | 1 | No | R/ NR DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3482064; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ NON-URTICARIAL MACULAR RASH WITH BLANCHING ERYTHEMA ON LEFT DELTOID | 2020-08-25 (9)/ 2020-09-04 (19) | Yes/ Yes/ No | 3 | No | R/ NR DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3482144; Age (years): 53; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ WORSENING RAISED, ERYTHEMATOUS ECZEMATOUS RASH BILATERALLY POSTERIOR TO THE KNEES | 2020-09-01 (7)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3482155; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ LEFT SIDED FACIAL SWELLING | 2020-10-31 (37)/ 2020-11-08 (45) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3492122; Age (years): 74; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH TO LEFT WRIST | 2020-10-16 (8)/ 2020-10-18 (10) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3512008; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH LEFT DELTOID, NON-URTICARIAL; MACULOPAPULAR | 2020-08-13 (9)/ 2020-08-18 (14) | Yes/ Yes/ No | 1 No | R/ R | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3512089; Age (years): 59; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ ERYTHEMATOUS RASH ON LOWER LUMBAR REGION NON-URTICARIAL | 2020-08-19 (5)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3512177; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ ATYPICAL DERMATITIS: LEFT POSTERIOR SCALP ITCHINESS | 2020-10-03 (9)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3512233; Age (years): 50; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ PAPULAR, URTICARIAL INJECTION SITE ERYTHEMA RIGHT DELTOID | 2020-09-12 (8)/ 2020-09-13 (9) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR, NON-URTICARIAL RASH ON LEFT CHEST AND NECK | 2020-09-14 (10)/ 2020-09-15 (11) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3522038; Age (years): 49; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ DIFFUSE ERYTHEMATOUS RASH (RIGHT SIDE OF BODY) | 2020-08-18 (13)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3522103; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ LEFT ARM RASH | 2020-09-14 (4)/ 2020-09-15 (5) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3522435; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ BILATERAL FOOT ERYTHROMACULAR RASH, NON-URTICARIAL | 2020-09-10 (14) / 2020-09-10 (14) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3522603; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH-BILATERAL ARMPITS | 2020-10-04 (27) / Ongoing | Yes/ No/ No | 1 No | NR/ NA | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3522603; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RIGHT LATERAL RIB SKIN RASH | 2020-10-04 (27)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3522609; Age (years): 46; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ EAR DERMATITIS (LEFT) | 2020-09-14 (7)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3522615; Age (years): 24; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ CIRCULAR RASH AROUND INJECTION SITE WITH PRURITUS | 2020-09-18 (11)/ Ongoing | Yes/ No/ Yes | 1 No | R/ NR | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3522677; Age (years): 44; Sex: M; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Injury, poisoning and procedural complications/ Injection related reaction/ CHILLS DAY 8 POST 2ND INJECTION | 2020-10-23 (8)/ Ongoing | Yes/ No/ Yes | 1 No | R/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3532092; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON LEFT ARM, MACULAR, URTICARIAL | 2020-09-01 (13)/ 2020-09-06 (18) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3532122; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON NECK AND ABDOMEN, NON-PAPULAR, NON- URTICARIAL | 2020-08-26 (3)/ 2020-08-27 (4) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3532122; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON NECK AND ABDOMEN, NON-PAPULAR, NON-URTICARIAL | 2020-09-22 (2)/ 2020-09-23 (3) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3532149; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR RASH ON CLAVICLES, NON-URTICARIAL | 2020-09-04 (10)/ 2020-09-06 (12) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3532219; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Rhinitis allergic/ ALLERGIC RHINITIS | 2020-09-22 (21)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3532225; Age (years): 69; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ STRESS RELATED SKIN RASH ON SHOULDERS, BACK AND GENITAL AREA | 2020-10-19 (20)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3542108; Age (years): 46; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ CHEEK SWELLING, BILATERAL | 2020-09-30 10:00 (1)/ 2020-10-05 (7) | Yes/ Yes/ No | 2 Yes/6 | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3542148; Age (years): 69; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY RASH (RIGHT FOREARM) - NON-URTICARIAL | 2020-10-12 (12)/ 2020-10-21 (21) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3542280; Age (years): 39; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR RASH (TRUNK, ARMS) - NON-URTICARIAL | 2020-10-03 (11)/ 2020-10-04 (12) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3552131; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON NECK AND SHOULDERS- MACULAR AND URTICARIAL | 2020-09-30 (13)/ 2020-10-06 (19) | Yes/ No/ No | 1 No | R/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3552355; Age (years): 53; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Eye swelling/ SWOLLEN EYES | 2020-10-06 15:00 (2) / 2020-10-08 (4) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3552451; Age (years): 25; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON ARMS AND LEGS | 2020-09-26 (10) / 2020-10-05 (19) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3552497; Age (years): 22; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH TO LEFT ARM | 2020-10-03 (8) / 2020-10-06 (11) | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3562081; Age (years): 51; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH INJECTION SITE | 2020-09-03 (9) / 2020-09-03 (9) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3562188; Age (years): 36; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH PATCHY UPPER BODY NON URTICARIAL | 2020-10-10 (20) / 2020-10-13 (23) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|-------------------------|
| Subject ID: US3572270; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-10-22 (14) / 2020-10-24 (16) | Yes/ Yes/ No | 3 No | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3572396; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-11-14 (4) / 2020-11-16 (6) | Yes/ No/ No | 1 No | / NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3582060; Age (years): 73; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ REDNESS AT INJECTION SITE - MACULOPAPULAR RASH, NON-URTICARIAL | 2020-09-05 (10)/ 2020-09-12 (17) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3582093; Age (years): 66; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ RASH/RED BUMP ON LEFT UPPER ARM | 2020-09-15 (14)/ 2020-09-16 (15) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3582126; Age (years): 34; Sex: M; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ MACULOPAPULAR LEFT SHOULDER (DELTOID) RASH, NON-URTICARIAE | 2020-09-18 (10)/ 2020-09-20 (12) | Yes/ No/ No | 1 | No | R/ NR DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3582127; Age (years): 30; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ LEFT UPPER ARM RASH, MACULOPAPULAR, NON-URTICARIAL | 2020-09-17 (9)/ 2020-09-25 (17) | Yes/ Yes/ No | 1 | No | R/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3592137; Age (years): 37; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ RASH PRURITIC BILATERAL LOWER EXTREMITY, RIGHT FOREARM | 2020-08-26 (15)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3602122; Age (years): 56; Sex: F; Race: OTHER: (b) (6) RACE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| General disorders and administration site conditions/ Injection site rash/ 2 X 3 CM RASH AT THE INJECTION SITE | 2020-10-10 06:00 (8)/ Ongoing | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3622041; Age (years): 67; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ PRURITIC PATCH/RASH | 2020-09-17 (3) / 2020-09-24 (10) | Yes/ No/ No | 2 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3622062; Age (years): 21; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Hand dermatitis/ HAND DERMATITIS (BILATERAL) | 2020-08-31 (10) / 2020-09-02 (12) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3622082; Age (years): 48; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVE | 2020-09-02 (8) / 2020-09-02 (8) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|---|---|--------------------------|
| Subject ID: US3632003; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS | 2020-10-10 (23)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3632010; Age (years): 42; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS ON LEFT SIDE OF NECK | 2020-10-10 (18)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3632010; Age (years): 42; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS AT LEFT EYE BROW LINE | 2020-10-10 (18)/ 2020-10-13 (21) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3632066; Age (years): 66; Sex: M; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ SWOLLEN RIGHT EYE LIDS | 2020-10-07 (3)/ 2020-10-09 (5) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3642250; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH FROM VACCINE #1 | 2020-09-26 (8)/ 2020-09-29 (11) | Yes/ No/ No | 3 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3672003; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ (PAPULAR URTICARIA) REDNESS @ SITE OF INJECTION (LEFT ARM) | 2020-08-14 (9)/ 2020-08-17 (12) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3672105; Age (years): 29; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS DUE TO POISON IVY (MEDIAL LEFT CALF) | 2020-08-24 (12)/ 2020-09-08 (27) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3672163; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RIGHT ARM ERYTHEMA (URTICARIAL) | 2020-08-26 (9)/ Ongoing | Yes/ Yes/ No | 2 No | R/ NR | DRUG WITHDRAWN/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3672261; Age (years): 27; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| General disorders and administration site conditions/ Swelling face/ RIGHT LOWER FACE SWELLING. | 2020-09-08 (19)/ 2020-09-16 (27) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3672377; Age (years): 31; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA | 2020-09-18 (22)/ 2020-09-19 (23) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3672377; Age (years): 31; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ WORSENING OF URITICARIA | 2020-09-21 (25)/ Ongoing | Yes/ Yes/ No | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3682077; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ MACULAR NON-URTICARIAL RASH, TORSO | 2020-10-09 (3)/ 2020-10-11 (5) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3682079; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ DIFFUSE URTICARIA (HIVES) | 2020-11-15 (41)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3692053; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site urticaria/ INJECTION SITE HIVES, LEFT ARM | 2020-09-11 (8)/ 2020-09-11 (8) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|------------------------------|------------------------|
| Subject ID: US3692087; Age (years): 39; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ LEFT ARM RASH (RED PATCHY THAT ITCHES AND FEELS HOT) | 2020-09-16 (8)/ 2020-09-18 (10) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3692090; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RIGHT ARM RASH (95 MM). RED, ITCHY, AND SLIGHTLY RAISED. | 2020-09-23 (14)/ 2020-09-26 (17) | Yes/ No/ No | 2 No | R/ R | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3692123; Age (years): 36; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash macular/ RASH ON LEFT ARM -- NON-URTICARIAL, MACULAR. | 2020-09-24 (9) / 2020-09-30 (15) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3702013; Age (years): 67; Sex: M; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH AT INJECTION SITE | 2020-10-08 (1) / 2020-10-10 (3) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3722020; Age (years): 39; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH- RIGHT NECK AND ELBOW | 2020-09-19 (22)/ 2020-10-05 (38) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3722236; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Drug hypersensitivity/ MACROBID ALLERGY | 2020-09-16 (35)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash/ RASH | 2020-09-16 (35)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3732027; Age (years): 33; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ GENERAL BODY RASH | 2020-09-27 (24)/ 2020-10-03 (30) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3732041; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ EXACERBATION OF ENVIRONMENTAL ALLERGIES | 2020-08-11 (1)/ 2020-08-11 (1) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3732327; Age (years): 40; Sex: M; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RIGHT FOREARM RASH | 2020-10-02 (19)/ 2020-10-09 (26) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3742217; Age (years): 61; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash vesicular/ LEFT FOREARM VESICULAR RASH | 2020-10-29 (31)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3742223; Age (years): 29; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-09-29 (27)/ 2020-10-10 (38) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3742224; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash erythematous/ NON-URTICARIAL LOCALIZED ERYTHEMIC RASH LATERAL TO VACCINATION SITE | 2020-09-10 (8)/ 2020-09-13 (11) | Yes/ No/ No | 2 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3742375; Age (years): 39; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-27 (12)/ 2020-10-27 (12) | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|----------------------------|------------------------|
| Subject ID: US3742438; Age (years): 53; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ DIFFUSE TRANSIENT RASH | 2020-10-24 (8)/ 2020-11-08 (23) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3742439; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| General disorders and administration site conditions/ Vaccination site rash/ RASH ON LEFT ARM AT VACCINATION SITE | 2020-10-21 (5)/ 2020-10-23 (7) | Yes/ No/ No | 1 No | R/ R | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3742453; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ RASH TO NECK POPULAR, URTICARIAL | 2020-09-30 (9) / 2020-10-22 (31) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3752010; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Swollen tongue/ SWOLLEN TONGUE WITH UNUSUAL SENSATIONS | 2020-09-09 (2) / Ongoing | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|------------------------|
| Subject ID: US3762064; Age (years): 70; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY ON ARMS | 2020-09-06 (12)/ 2020-09-10 (16) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3762117; Age (years): 62; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ PARTICIPANT REPORTED AN ITCHING RASH ON BACK AND STOMACH THAT LASTED A COUPLE OF DAYS. NO TREATMENT. SAID COULD BE RELATED TO 5-MILE WALK IN HEAT. | 2020-09-04 (5)/ 2020-09-05 (6) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3762131; Age (years): 48; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS WORSENING | 2020-09-08 (8)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3762140; Age (years): 69; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH FROM INJECTION SITE TO ELBOW NON-URTICARIAL | 2020-09-12 (12)/ 2020-09-16 (16) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3772008; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis atopic/ ATOPIC DERMATITIS (UPPER AND LOWER LIMBS) | 2020-09-23 (16) / 2020-09-27 (20) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3772057; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS | 2020-10-28 (42) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3782039; Age (years): 62; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS- POISON IVY | 2020-09-01 (15)/ 2020-09-06 (20) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3802108; Age (years): 76; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH DISTAL INJECTION SITE | 2020-10-06 (8)/ Ongoing | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3802186; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-23 (15)/ 2020-10-07 (29) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3802226; Age (years): 20; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ ITCHY RASH TO HANDS AND FEET | 2020-11-08 (32)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3812010; Age (years): 71; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ NON-URTICARIAL MACULOPAPULAR RASH TO LEFT UPPER ARM (BELOW INJECTION SITE) | 2020-08-12 (10)/ 2020-08-14 (12) | Yes/ Yes/ No | 2 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3812022; Age (years): 70; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEEL]-URTICARIAL | 2020-08-12 (9)/ 2020-08-16 (13) | Yes/ Yes/ No | 1 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3812022; Age (years): 70; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEEL]-URTICARIAL | 2020-09-01 11:00 (1)/ 2020-09-06 22:00 (7) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3812091; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ BILATERAL THIGHS CONTACT DERMATITIS (POISON IVY) | 2020-08-21 (14)/ 2020-09-16 (40) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3812132; Age (years): 72; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ DERMATITIS ON LEFT ARM | 2020-09-09 09:00 (1)/ 2020-09-17 09:00 (9) | Yes/ Yes/ No | 3 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3812158; Age (years): 38; Sex: M; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis/ GENERALIZED DERMATITIS | 2020-09-12 (3)/ Ongoing | Yes/ Yes/ No | 2 No | R/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3812207; Age (years): 59; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Eczema/ ECZEMA EXACERBATION | 2020-09-17 (2)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3812281; Age (years): 20; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ WORSENING ENVIRONMENTAL ALLERGIES | 2020-09-20 (25)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERING/ RESOLVING |
| Subject ID: US3812338; Age (years): 36; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash maculo-papular/ PRURITIC MACULOPAPULAR RASH OF BUE AND BLE | 2020-10-09 (22)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3822003; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH (RIGHT ARM) | 2020-09-16 (16)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3822269; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY | 2020-09-15 (21)/ 2020-09-20 (26) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3822341; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ NON-URTICARIAL RASH ALONG LOWER SPINE | 2020-09-14 (14)/ 2020-09-18 (18) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3832088; Age (years): 59; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY DERMATITIS | 2020-09-11 (11)/ 2020-09-26 (26) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3832222; Age (years): 57; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ CONTACT DERMATITIS - FACE | 2020-08-20 15:00 (2)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3852119; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH- LEFT ANKLE | 2020-10-18 (11)/ 2020-10-22 (15) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3862104; Age (years): 67; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ EXACERBATION OF ENVIRONMENTAL ALLERGIES | 2020-10-11 (7)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3862175; Age (years): 51; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash pruritic/ RASH [ERYTHEMATOUS AND PRURITIC] OF VACCINATED ARM | 2020-09-13 (3)/ 2020-10-02 (22) | Yes/ No/ No | 1 No | R/ NR | DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3862188; Age (years): 32; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASHES ON LEFT FOREARM | 2020-11-07 (27)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3862257; Age (years): 42; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis allergic/ ALLERGIC DERMATITS | 2020-10-03 (5) / 2020-10-09 (11) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3862285; Age (years): 61; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ INJECTION SITE RASH | 2020-10-17 (3) / 2020-10-19 (5) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3872198; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ BODY RASH | 2020-10-31 (46) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3872372; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-20 (12) / 2020-10-23 (15) | Yes/ No/ No | 1 No | R/ NA | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3872440; Age (years): 35; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RIGHT ARM RASH AT INJECTION SITE RIGHT ARM NON URTICARIAL | 2020-09-11 (9) / 2020-09-13 (11) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3872480; Age (years): 35; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ BILATERAL SWOLLEN UPPER EYELIDS | 2020-09-14 (6) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Eye disorders/ Swelling of eyelid/ BILATERAL EYE LID SWELLING | 2020-09-14 (6) / 2020-09-21 (13) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3902030; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Lip swelling/ SWOLLEN LIPS | 2020-09-05 (3) / 2020-09-08 (6) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3902030; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-05 (3) / 2020-09-21 (19) | Yes/ Yes/ No | 1 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3902089; Age (years): 71; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON RIGHT LEG | 2020-10-22 (9) / 2020-10-23 (10) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3912068; Age (years): 69; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-12 (14) / 2020-10-12 (14) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3912116; Age (years): 58; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON INSIDE OF LEFT ARM | 2020-09-07 (4) / 2020-09-22 (19) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3922044; Age (years): 69; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ POISON IVY BILATERAL LOWER LEGS | 2020-09-15 (20) / 2020-09-23 (28) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3922084; Age (years): 42; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA | 2020-10-18 (10) / 2020-10-25 (17) | Yes/ No/ No | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3932008; Age (years): 76; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ BODY RASH | 2020-09-05 (11) / 2020-09-09 (15) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Rash/ BODY RASH | 2020-09-29 (2) / Ongoing | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3932018; Age (years): 47; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ON BILATERAL LEGS | 2020-10-10 (17)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3932055; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Lip swelling/ TOP LIP SWELLING | 2020-10-02 (2)/ 2020-10-03 (3) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3932130; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH 1/2 INCH FROM INJECTION SITE | 2020-09-24 (11)/ 2020-10-08 (25) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3932250; Age (years): 75; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ RASH AT INJECTION SITE | 2020-10-20 (7)/ 2020-10-24 (11) | Yes/ No/ Yes | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3952118; Age (years): 33; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Immune system disorders/ Hypersensitivity/ COLD HYPERSENSITIVITY OF BILATERAL HANDS AND TOES | 2020-09-21 11:30 (1) / 2020-09-23 (3) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3972046; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Injection site rash/ LEFT SHOULDER REDNESS (MACULOPAPULAR/NON-URTIC ARIAL) OF SITE INJECTION | 2020-09-04 (9) / 2020-09-08 (13) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3972071; Age (years): 69; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Allergic sinusitis/ ALLERGIC SINUSITIS | 2020-10-12 (15)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3972224; Age (years): 27; Sex: M; Race: OTHER: (b) (6) Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES ON ARM AND BACK | 2020-10-14 (3)/ 2020-10-19 (8) | Yes/ No/ No | 1 No | R/ NR | DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3982179; Age (years): 54; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Dermatitis contact/ SKIN DERMATITIS, CONTACT OF ABDOMEN | 2020-09-30 (15)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3992014; Age (years): 21; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Rash/ RASH ARMPITS | 2020-10-19 19:00 (1)/ Ongoing | Yes/ Yes/ Yes | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ ITCHY HIVES ON ARMS | 2020-10-19 19:00 (1)/ Ongoing | Yes/ Yes/ Yes | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020719.sas 03DEC2020 06:16

Listing 16.2.7.19
Unsolicited Adverse Events – Hypersensitivity
Safety Set

Hypersensitivity is identified through selected SMQ.

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---|--|--|
| Subject ID: US3012082; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS RIGHT KNEE | 2020-08-18 (12) / 2020-09-28 (53) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3022291; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF RIGHT KNEE ARTHRITIS | 2020-11-09 (43) / 2020-11-12 (46) | Yes/ Yes/ No | 4 Yes/3 (2020-11-09/ 2020-11-12) | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|--|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3082095; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS [BOTH KNEES] | 2020-11-03 (43) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3082237; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Periarthritis/ "FROZEN" SHOULDER | 2020-10-07 (24) / 2020-10-29 (46) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3102206; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS | 2020-11-07 (58)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3152082; Age (years): 38; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS | 2020-11-09 (47)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3162016; Age (years): 81; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS LEFT KNEE | / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3162030; Age (years): 75; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS OF BILATERAL HANDS | 2020-09-01 (6)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|--|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3162158; Age (years): 57; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ WORSENING OF GOUT (GOUT ATTACK) RIGHT ANKLE | 2020-08-24 (5) / 2020-09-29 (41) | Yes/ Yes/ No | 2 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3162205; Age (years): 70; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT FLARE RIGHT GREAT TOE | 2020-10-01 (4) / 2020-10-09 (12) | Yes/ No/ No | 2 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3212096; Age (years): 67; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF LEFT KNEE DEGENERATIVE JOINT DISEASE | 2020-10-09 (32) / 2020-10-10 (33) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3212149; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF RIGHT KNEE OSTEOARTHRITIS PAIN | 2020-08-20 (9) / 2020-08-27 (16) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3212166; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ WORSENING OF OSTEOARTHRITIS OF LUMBAR SPINE | 2020-09-14 (6) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3252465; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS | 2020-10-13 00:00 (32) / 2020-10-13 16:00 (33) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|--|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3272274; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS IN LEFT THUMB | 2020-10-15 (20) / 2020-11-09 (45) | Yes/ Yes/ No | 2 No | NR/ NR NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3292320; Age (years): 54; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ BILATERAL HIP OSTEOARTHRITIS | 2020-08-30 (6) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR DOSE NOT CHANGED/ NONE | UNKNOWN |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3322139; Age (years): 40; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT | 2020-09-18 (15)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3342343; Age (years): 61; Sex: F; Race: UNKNOWN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Synovitis/ NEW ONSET OF SYMMETRICAL SYNOVITIS OF HANDS AND FEET | 2020-10-26 (15)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|--------------------------|
| Subject ID: US3412158; Age (years): 73; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ CHRONIC OSTEOARTHRITIS (WORSENSING) - KNEES, SHOULDER AND WRIST | 2020-08-28 (23)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | UNKNOWN |
| Subject ID: US3422038; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS | 2020-11-23 (70)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|--|-----------------------------------|---|--|--|------------------------|
| Subject ID: US3422230; Age (years): 81; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ SYNVISC KNEE INJECTION FOR OSTEOARTHRITIS | 2020-09-28 (21) / 2020-09-28 (21) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3422281; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS | 2020-10-27 (14) / 2020-10-28 (15) | Yes/ Yes/ No | 3 Yes/3 (2020-10-27/ 2020-10-28) | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---|--|---|------------------------|
| Subject ID: US3472004; Age (years): 47; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT FLAREUP - RIGHT GREAT TOE | 2020-09-05 (6) / 2020-09-06 (7) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3482145; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION IN RIGHT KNEE | 2020-09-26 (32) / 2020-09-30 (36) | Yes/ Yes/ No | 3 Yes/3 (2020-09-26/ 2020-09-30) | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3492081; Age (years): 90; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ MUSCLE ACHES OF THE NECK (RELATED TO OSTEOARTHRITIS) | 2020-10-02 (25) / 2020-10-02 (25) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3492162; Age (years): 68; Sex: F; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS L KNEE | 2020-10-29 (14) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3502177; Age (years): 50; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION | 2020-10-03 (9) / 2020-10-08 (14) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3522128; Age (years): 70; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT FLAIR | 2020-10-10 (30) / 2020-10-11 (31) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3542159; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ EXACERBATION OF OSTEOARTHRITIS | 2020-10-25 (21) / 2020-10-26 (22) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3562132; Age (years): 75; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS BILATERAL HANDS | 2020-10-01 (23) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3662094; Age (years): 81; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT-TOE | 2020-09-30 (17) / 2020-10-10 (27) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3672215; Age (years): 24; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TEMPOROMANDIBULAR JOINT DISORDER | 2020-09-09 (21) / 2020-09-17 (29) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|--|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3722034; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ MULTILEVEL LUMBAR SPONDYLOSIS | 2020-09-01 (2) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3742363; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ POLYARTHRITIS ON L/R HANDS | 2020-09-22 (6) / Ongoing | Yes/ No/ No | 2 No | R/ R | NOT APPLICABLE/ NONE | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|--|
| Subject ID: US3742363; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Polyarthritis/ POLYARTHRITIS L/R FEET | 2020-10-22 (8)/ Ongoing | Yes/ No/ No | 2 No | R/ R | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3812209; Age (years): 47; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT KNEE WORSENING OSTEOARTHRITIS | 2020-10-06 (21)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT PROCEDURE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3842017; Age (years): 40; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT FLARE UP (LEFT BIG TOE) | 2020-09-08 (5) / 2020-09-18 (15) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3872334; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT SHOULDER ULNOHUMERAL ARTHRITIS | 2020-09-22 (27) / 2020-09-23 (28) | Yes/ Yes/ No | 3 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---|--|---|
| Subject ID: US3912028; Age (years): 75; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS, LEFT SHOULDER | 2020-09-28 (32)/ 2020-09-28 (32) | Yes/ No/ No | 3 Yes/3 (2020-09-28/ 2020-09-29)/6 | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3922047; Age (years): 83; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS BILATERAL HANDS | 2020-09-11 (15)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---|--|--|
| Subject ID: US3022246; Age (years): 62; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT HIP ARRHRITIS | 2020-11-14 (52)/ 2020-11-15 (53) | Yes/ Yes/ No | 4 Yes/3 (2020-11-14/ 2020-11-15) | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3032103; Age (years): 38; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS | 2020-10-30 (57)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---|--|--|--------------------------------|
| Subject ID: US3042090; Age (years): 55; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING RIGHT KNEE PAIN INDUCED BY OSTEOARTHRITIS | 2020-08-20 (15)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3062151; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ LEFT HIP OSTEOARTHRITIS | 2020-10-14 (41)/ 2020-10-15 (42) | Yes/ Yes/ No | 4 Yes/3 (2020-10-14/ 2020-10-15) | NR/ NR | NOT APPLICABLE/ CONCOMITANT PROCEDURE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|--|
| Subject ID: US3062265; Age (years): 56; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT HIP DEGENERATIVE CHANGES | 2020-10-13 (21) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |
| Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ DEGENERATIVE SPONDYLOSIS | 2020-10-13 (21) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3112113; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ KNEE JOINT ASPIRATION DUE TO OSTEOARTHRITIS | 2020-11-10 (70)/ 2020-11-10 (70) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3182100; Age (years): 55; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ OSTEOARTHRITIS LEFT FOOT AND ANKLE | 2020-08-01 (3)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3312394; Age (years): 58; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Chondrocalcinosis pyrophosphate/ CALCIUM PYROPHOSPHATE DIHYDRATE CRYSTAL DEPOSITION DISEASE | 2020-11-04 (38) / 2020-11-11 (45) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3332002; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ WORSENING NECK OSTEOARTHRITIS PAIN | 2020-09-05 12:00 (1) / 2020-09-19 (16) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3342120; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Polyarthritis/ SUBACUTE SYMMETRICAL POLYARTHRITIS | 2020-09-30 (10) / Ongoing | Yes/ No/ No | 2 No | R/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3352114; Age (years): 61; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TEMPOROMANDIBULAR JOINT DYSFUNCTION | 2020-09-15 (29) / 2020-10-26 (70) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---|---|--|--|
| Subject ID: US3362244; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING OF LEFT HIP PAIN/ARTHRITIS | 2020-09-08 (16) / 2020-11-11 (80) | Yes/ Yes/ No | 2 No | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | RECOVERED/ RESOLVED |
| Subject ID: US3402139; Age (years): 55; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ WORSENING LEFT KNEE ARTHRITIS | 2020-08-09 (9) / 2020-10-14 (75) | Yes/ Yes/ No | 2 Yes/3 (2020-10-12/ 2020-10-14) | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT UNDERGOING PHYSICAL THERAPY |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3402233; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ WORSENING OF RIGHT FOOT GOUT | 2020-10-05 (34)/ Ongoing | Yes/ Yes/ No | 2 No | NA/ NR | NOT APPLICABLE/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3422127; Age (years): 40; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Spinal osteoarthritis/ OSTEOARTHRITIS IN LOWER BACK | 2020-10-03 (10)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3432288; Age (years): 70; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ L SHOULDER ARTHRITIS | 2020-09-29 (2)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3442147; Age (years): 60; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OSTEOARTHRITIS BILATERAL KNEE | 2020-11-02 (15)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3482278; Age (years): 52; Sex: F; Race: MULTIPLE (b) (6) | | | | | |
| (b) (6) Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ LEFT THUMB CARPO-METACARPAL ARTHRTIS , REQUIRING LOCAL JOINT STEROID INJECTION | 2020-10-07 (27)/ Ongoing | Yes/ Yes/ No | 2 | No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3492022; Age (years): 74; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT | 2020-10-23 (29)/ 2020-11-13 (50) | Yes/ No/ No | 3 | No | NR/ NR DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3522346; Age (years): 81; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Spondylitis/ DIAGNOSED WITH ARTHRITIS IN SPINE | 2020-10-19 (21)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |
| Subject ID: US3522401; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ RIGHT THUMB ARTHRITIS | 2020-09-11 (16)/ Ongoing | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3532271; Age (years): 79; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT FLARE UP IN TOE | 2020-09-10 07:00 (1) / 2020-09-12 00:00 (3) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3582049; Age (years): 48; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT EXACERBATION | 2020-09-13 (19) / 2020-09-17 (23) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3592245; Age (years): 71; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ Gout/ GOUT RIGHT GREAT TOE | 2020-09-04 (7) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|-------------------------------|--|---|--------------------------------|
| Subject ID: US3622075; Age (years): 73; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ HIP INFLAMMATION | 2020-09-30 (9) / 2020-10-06 (15) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3662036; Age (years): 61; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ OTHER SPECIFIED ARTHRITIS, MULTIPLE SITES (BOTH KNEES) | 2020-10-27 (30) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3732283; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ EXACERBATION OF ARTHRITIS | 2020-11-05 (31)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3742169; Age (years): 57; Sex: M; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Rheumatoid arthritis/ RHEUMATOID ARTHRITIS | 2020-08-31 23:00 (1)/ Ongoing | Yes/ Yes/ No | 2 Yes/6 | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3752153; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS (UNKNOWN LOCATION) | 2020-08-20 (2)/ 2020-08-29 (11) | Yes/ No/ No | 1 No | R/ R DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3802008; Age (years): 66; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Periarthritis/ SCHEDULED LEFT FROZEN SHOULDER | 2020-08-19 15:00 (2)/ 2020-08-19 16:00 (2) | Yes/ Yes/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|---------------------------|---|--|--------------------------------|
| Subject ID: US3812091; Age (years): 72; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ RIGHT HALLUX DEGENERATIVE JOINT DISEASE | 2020-09-14 (11) / 2020-10-28 (55) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | RECOVERED/ RESOLVED |
| Subject ID: US3822066; Age (years): 58; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ INFLAMMATORY ARTHRITIS | 2020-10-06 (23) / Ongoing | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3822074; Age (years): 37; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Temporomandibular joint syndrome/ TMJ EXACERBATION | 2020-08-12 (2)/ Ongoing | Yes/ No/ No | 3 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3832060; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS | 2020-09-24 (25) / 2020-09-24 (25) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED WITH SEQUELAE: SUBJECT REPORTED GETTING CORTISONE INJECTIONS IN BOTH KNEES FOR WORSENING OF OSTEOARTHRITIS . SUBJECT REPORTS THAT THE INJECTIONS HAVE HELPED. SUBJECT TO CONTINUE IN |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3832060; Age (years): 53; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS | 2020-10-24 (55)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3862063; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Arthritis/ EXACERBATION OF CHRONIC RECURRENT INFLAMMATION OF RIGHT KNEE | 2020-09-14 (20)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3942007; Age (years): 52; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Musculoskeletal and connective tissue disorders/ Osteoarthritis/ WORSENING OF OSTEOARTHRITIS TO THE LEFT KNEE | 2020-11-17 (57)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020720.sas 03DEC2020 06:16

Listing 16.2.7.20
Unsolicited Adverse Events – Arthritis
Safety Set

Arthritis is identified through selected SMQ.

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3002216; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ACE INHIBITOR INDUCED ANGIOEDEMA | 2020-09-11 (12) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3032171; Age (years): 52; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIA | 2020-09-13 (35) / 2020-09-24 (46) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3102340; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES RT ELBOW AND CHEST | 2020-09-27 (17) / 2020-10-04 (24) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3112362; Age (years): 30; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-19 (27) / 2020-09-19 (27) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3282080; Age (years): 68; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES TO GLUTEUS MAXIMUS | 2020-09-26 (33) / 2020-09-26 (33) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---|--|--|
| Subject ID: US3292339; Age (years): 70; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA | 2020-09-16 (21)/ 2020-09-18 (23) | Yes/ Yes/ No | 4 Yes/2/3 (2020-09-17/ 2020-09-18) | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |
| Subject ID: US3292383; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BILATERAL FOREARMS | 2020-09-12 (15)/ 2020-09-25 (28) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|--|-----------------------------------|---------------------------|-------------------------------|---|------------------------|
| Subject ID: US3352099; Age (years): 30; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Gastrointestinal disorders/ Palatal oedema/ UVULA EDEMA | 2020-10-13 (27) / 2020-10-18 (32) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3412319; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL - RASH - BILATERAL FOREARMS | 2020-09-16 (23) / 2020-09-19 (26) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3442217; Age (years): 60; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-14 (9) / 2020-11-19 (45) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---|--|---|
| Subject ID: US3462111; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Respiratory, thoracic and mediastinal disorders/ Laryngeal oedema/ LARYNGEAL EDEMA | 2020-09-19 (5) / 2020-09-24 (10) | Yes/ Yes/ No | 4 Yes/3 (2020-09-19/ 2020-09-20) | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3482086; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL UPPER CHEST RASH | 2020-09-22 (7) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|---|--------------------------------|
| Subject ID: US3512009; Age (years): 78; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Gastrointestinal disorders/ Lip swelling/ ALLERGIC REACTION OF INTERMITTENT LIP SWELLING | 2020-09-17 (2)/ Ongoing | Yes/ Yes/ Yes | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE AND NECK | 2020-08-31 (3)/ Ongoing | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3512176; Age (years): 71; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK) | 2020-08-31 (3)/ 2020-10-04 (37) | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES (FACE AND NECK) | 2020-10-08 (41)/ Ongoing | Yes/ No/ No | 1 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3522233; Age (years): 21; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ URTICARIAL, PAPULAR RASH, UNKNOWN ETIOLOGY | 2020-10-07 (16) / 2020-10-25 (34) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3522467; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ INTERMITTENT HIVES ON FACE/NECK | 2020-09-18 (19) / Ongoing | Yes/ No/ No | 1 No | R/ NA | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3532031; Age (years): 66; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Periorbital oedema/ BILATERAL PERIORBITAL EDEMA | 2020-09-04 (22)/ 2020-09-05 (23) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3532114; Age (years): 55; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PRURITIC PAPULES- BILATERAL ARMS AND LEGS, ABDOMEN | 2020-08-23 (3)/ 2020-10-27 (68) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3552303; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL MACULAR PAPULAR RASH ON RIGHT ARM | 2020-09-13 (12)/ 2020-09-17 (16) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3552530; Age (years): 33; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED URTICARIAL RASH | 2020-10-18 (5)/ 2020-11-13 (31) | Yes/ Yes/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3582154; Age (years): 29; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA | 2020-09-23 (6) / 2020-09-26 (9) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3602030; Age (years): 41; Sex: F; Race: UNKNOWN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ SWELLING TO THE RIGHT SIDE OF THE FACE | 2020-09-17 (7) / 2020-09-27 (17) | Yes/ Yes/ No | 2 Yes/6 | R/ NR | DOSE NOT CHANGED/ CONCOMITANT PROCEDURE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3602034; Age (years): 38; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ BILATERAL EYELID PUFFINESS | 2020-10-27 (19) / 2020-10-29 (21) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Eye disorders/ Swelling of eyelid/ BILATERAL EYELID SWELLING | 2020-10-27 (19) / 2020-10-29 (21) | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|--|
| Subject ID: US3602084; Age (years): 42; Sex: M; Race: OTHER: NOT SPECIFIED BY SUBJECT; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ SWELLING ON LEFT SIDE OF CHEEK | 2020-10-08 (17) / 2020-10-17 (26) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ BILATERAL HAND RASH-- DORSUM WITH HIVES | 2020-11-03 (14) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3602084; Age (years): 42; Sex: M; Race: OTHER: NOT SPECIFIED BY SUBJECT; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Periorbital swelling/ BILATERAL PUFFY EYES | 2020-11-03 (14) / 2020-11-04 (15) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3622191; Age (years): 20; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Gingival swelling/ LEFT LOWER JAW GUM SWELLING/PUS (BEHIND WISDOM TOOTH) | 2020-10-27 (14) / 2020-11-11 (29) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3662019; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Periorbital swelling/ PERI-ORBITAL SWELLING | 2020-09-10 (15) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|---|--|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3662083; Age (years): 71; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH DISSEMINATED-URTICARIA | 2020-09-29 (19) / 2020-09-30 (20) | Yes/ No/ No | 2 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3682138; Age (years): 47; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ WELTS - ITCHY - ABODEMN AND ARMS | 2020-10-24 (13) / 2020-10-28 (17) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3712086; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA RASH (HIVES) (ANTERIOR UPPER AND LOWER ARM) | 2020-09-16 02:00 (1)/ 2020-09-25 18:00 (11) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3742123; Age (years): 36; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BILATERAL ARMS | 2020-10-05 (33)/ 2020-10-09 (37) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3742341; Age (years): 50; Sex: M; Race: NOT REPORTED; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH | 2020-09-12 05:00 (1)/ Ongoing | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |
| Subject ID: US3752250; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Lip swelling/ LIP SWELLING | 2020-09-12 (19)/ 2020-09-19 (26) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3752295; Age (years): 35; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES ON LEGS, ARMS, BACK, AND TORSO | 2020-09-20 (24)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3782073; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA | 2020-08-28 (5) / Ongoing | Yes/ Yes/ No | 3 No | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3802023; Age (years): 71; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ MACULAR GENERALIZED BILATERAL LEGS URTICARIAL RASH | 2020-09-19 (27) / 2020-10-06 (44) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3812044; Age (years): 60; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIA ON BACK AND BLE (DUE TO TICK BITES) | 2020-08-23 (19) / 2020-10-07 (64) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3822006; Age (years): 51; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Eye swelling/ SWELLING UNDER EYE, BILATERAL | 2020-08-09 (6) / Ongoing | Yes/ Yes/ No | 1 No | R/ R | DRUG WITHDRAWN/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3862137; Age (years): 82; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA RASH | 2020-10-29 (24) / Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3892032; Age (years): 64; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON MID BACK (URTICARIA) | 2020-11-12 (46) / Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---------------------------|--|---|--------------------------|
| Subject ID: US3902019; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON BUTTOCKS AND BILATERAL AXILLA | 2020-09-05 (4)/ Ongoing | Yes/ No/ No | 2 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3902064; Age (years): 50; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Eye disorders/ Eye swelling/ SWOLLEN RIGHT EYE | 2020-09-18 (9)/ 2020-09-25 (16) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Action Taken Relation-with IP/ ship to Other Action IP/SP [3] Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|------------------------|
| Subject ID: US3982143; Age (years): 44; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ SKIN RASH ON (L) SIDE OF NECK (URTICARIAL AND PAPULAR) | 2020-09-10 06:00 (1)/ 2020-09-13 06:00 (4) | Yes/ No/ No | 1 No | NR/ NR DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3982275; Age (years): 63; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Idiopathic urticaria/ IDIOPATHIC URTICARIA | 2020-10-21 (8)/ 2020-10-21 (8) | Yes/ Yes/ No | 1 No | NR/ NR DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3012246; Age (years): 21; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES (ALL OVER BODY) | 2020-10-25 (28)/ 2020-10-25 (28) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3082081; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-01 (11)/ 2020-10-05 (15) | Yes/ No/ No | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3122047; Age (years): 28; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HYPERSENSITIVITY RASH - BILATERAL ELBOWS (MACULAR - URTICARIAL) | 2020-08-04 (9) / 2020-08-11 (16) | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3162007; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA TRUNK | 2020-08-06 (11) / Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3172265; Age (years): 34; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ SKIN RASH (CONSISTENT WITH HIVES) (ARMS, LEGS, CHEST, AND BACK) | 2020-08-22 23:00 (2)/ 2020-08-25 05:00 (4) | Yes/ No/ No | 1 No | R/ R | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3192245; Age (years): 77; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA ON LEFT SIDE OF BODY INCLUDING ARM, LEG AND SOMETIMES LOWER ABDOMEN | 2020-10-16 (36)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|--|
| Subject ID: US3212316; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA OF THE STOMACH, BREASTS AND BILATERAL NECK. | 2020-09-24 (3) / 2020-09-26 (5) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3292059; Age (years): 42; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIA | 2020-09-18 (14) / 2020-10-01 (27) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3292241; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Eye swelling/ LEFT EYE SWELLING | 2020-08-21 (2) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3312014; Age (years): 40; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ GENERALIZED RAISED, URTICARIAL, ERYTHEMATOUS RASH (ON CHEST, STOMACH, PROXIMAL UPPER AND LOWER EXTREMITIES) | 2020-09-08 (2)/ 2020-09-10 (4) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3322219; Age (years): 62; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-04 (2)/ 2020-09-06 (4) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3322329; Age (years): 51; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ FACIAL SWELLING | 2020-10-17 (3)/ 2020-10-22 (8) | Yes/ Yes/ No | 3 Yes/6 | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3362023; Age (years): 55; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Swollen tongue/ TONGUE SWELLING - POST INJECTION ALLERGIC REACTION | 2020-08-03 16:20 (1)/ 2020-08-03 18:20 (1) | Yes/ Yes/ No | 2 No | R/ NR | DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3362280; Age (years): 57; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL RASH TO BACK | 2020-09-14 (6)/ 2020-09-16 (8) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ PAPULAR URTICARIAL RASH TO GROIN | 2020-10-09 (3)/ 2020-10-23 (17) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3432119; Age (years): 25; Sex: F; Race: MULTIPLE: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA LOCALIZED ON NECK AND CHEEK | 2020-09-15 (2) / 2020-09-16 (3) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3482155; Age (years): 38; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ LEFT SIDED FACIAL SWELLING | 2020-10-31 (37) / 2020-11-08 (45) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3532092; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON LEFT ARM, MACULAR, URTICARIAL | 2020-09-01 (13)/ 2020-09-06 (18) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3542108; Age (years): 46; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| General disorders and administration site conditions/ Swelling face/ CHEEK SWELLING, BILATERAL | 2020-09-30 10:00 (1)/ 2020-10-05 (7) | Yes/ Yes/ No | 2 Yes/6 | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|---|---|------------------------|
| Subject ID: US3552131; Age (years): 65; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH ON NECK AND SHOULDERS- MACULAR AND URTICARIAL | 2020-09-30 (13)/ 2020-10-06 (19) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |
| Subject ID: US3552355; Age (years): 53; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Eye disorders/ Eye swelling/ SWOLLEN EYES | 2020-10-06 15:00 (2)/ 2020-10-08 (4) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3552451; Age (years): 25; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH ON ARMS AND LEGS | 2020-09-26 (10) / 2020-10-05 (19) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3622082; Age (years): 48; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVE | 2020-09-02 (8) / 2020-09-02 (8) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3632066; Age (years): 66; Sex: M; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ SWOLLEN RIGHT EYE LIDS | 2020-10-07 (3) / 2020-10-09 (5) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3672163; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RIGHT ARM ERYTHEMA (URTICARIAL) | 2020-08-26 (9) / Ongoing | Yes/ Yes/ No | 2 No | R/ NR | DRUG WITHDRAWN/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3672261; Age (years): 27; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive | | | | | |
| General disorders and administration site conditions/ Swelling face/ RIGHT LOWER FACE SWELLING. | 2020-09-08 (19) / 2020-09-16 (27) | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation- with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3672377; Age (years): 31; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Angioedema/ ANGIOEDEMA | 2020-09-18 (22)/ 2020-09-19 (23) | Yes/ No/ No | 1 No | R/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ WORSENING OF URITICARIA | 2020-09-21 (25)/ Ongoing | Yes/ Yes/ No | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3682079; Age (years): 29; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ DIFFUSE URITICARIA (HIVES) | 2020-11-15 (41)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3742375; Age (years): 39; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-27 (12)/ 2020-10-27 (12) | Yes/ No/ No | 2 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3742453; Age (years): 58; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria papular/ RASH TO NECK POPULAR, URTICARIAL | 2020-09-30 (9)/ 2020-10-22 (31) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3752010; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Swollen tongue/ SWOLLEN TONGUE WITH UNUSUAL SENSATIONS | 2020-09-09 (2)/ Ongoing | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3802186; Age (years): 74; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-23 (15)/ 2020-10-07 (29) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3812022; Age (years): 70; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEEL]-URTICARIAL | 2020-08-12 (9) / 2020-08-16 (13) | Yes/ Yes/ No | 1 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ RASH LEFT UPPER ARM [WHEEL]-URTICARIAL | 2020-09-01 11:00 (1) / 2020-09-06 22:00 (7) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3822003; Age (years): 65; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIAL RASH (RIGHT ARM) | 2020-09-16 (16) / Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3872372; Age (years): 47; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-20 (12) / 2020-10-23 (15) | Yes/ No/ No | 1 No | R/ NA | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3872480; Age (years): 35; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ BILATERAL SWOLLEN UPPER EYELIDS | 2020-09-14 (6) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3872480; Age (years): 35; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Eye disorders/ Swelling of eyelid/ BILATERAL EYE LID SWELLING | 2020-09-14 (6) / 2020-09-21 (13) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3902030; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Lip swelling/ SWOLLEN LIPS | 2020-09-05 (3) / 2020-09-08 (6) | Yes/ No/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-09-05 (3) / 2020-09-21 (19) | Yes/ Yes/ No | 1 No | R/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3912068; Age (years): 69; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES | 2020-10-12 (14) / 2020-10-12 (14) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3922084; Age (years): 42; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ URTICARIA | 2020-10-18 (10) / 2020-10-25 (17) | Yes/ No/ No | 2 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3932055; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Lip swelling/ TOP LIP SWELLING | 2020-10-02 (2) / 2020-10-03 (3) | Yes/ No/ No | 1 No | R/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|---------------------------|--|---|
| Subject ID: US3972224; Age (years): 27; Sex: M; Race: OTHER: (b) (6); Baseline SARS-CoV-2 Status: Positive | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ HIVES ON ARM AND BACK | 2020-10-14 (3) / 2020-10-19 (8) | Yes/ No/ No | 1 No | R/ NR | DRUG WITHDRAWN/ NONE RECOVERED/ RESOLVED |
| Subject ID: US3992014; Age (years): 21; Sex: F; Race: ASIAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Skin and subcutaneous tissue disorders/ Urticaria/ ITCHY HIVES ON ARMS | 2020-10-19 19:00 (1) / Ongoing | Yes/ Yes/ Yes | 2 No | R/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020721.sas 03DEC2020 06:16

Listing 16.2.7.21
Unsolicited Adverse Events – Angioedema
Safety Set

Angioedema is identified through selected SMQ.

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.22
Unsolicited Adverse Events – Peripheral Neuropathy
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3202097; Age (years): 41; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ 2020-09-29 Neuralgia/ (19)/ NERVE PAIN IN NECK Ongoing | | Yes/ Yes/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION | RECOVERING/ RESOLVING |
| Subject ID: US3372121; Age (years): 68; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ 2020-08-27 Neuralgia/ (15)/ RIGHT HAND NERVE PAIN Ongoing | | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Nervous system disorders/ 2020-08-27 Neuralgia/ (15)/ LEFT HAND NERVE PAIN 2020-09-24 (43) | | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3642018; Age (years): 74; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ / Neuropathy peripheral/ Ongoing NEUROPATHY | | Yes/ Yes/ No | 2 No | R/ NR | DOSE NOT CHANGED/ NONE | RECOVERING/ RESOLVING |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020722.sas 03DEC2020 06:16

Listing 16.2.7.22
Unsolicited Adverse Events – Peripheral Neuropathy
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|---|---|--------------------------------|
| Subject ID: US3782168; Age (years): 43; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Neuropathy peripheral/ POSSIBLE PERIPHERAL NEUROPATHY | 2020-11-18 (37)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3812021; Age (years): 68; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Neuralgia/ NERVE PAIN NEAR RIGHT TEMPLE | 2020-09-01 19:00 (1)/ 2020-09-02 22:30 (2) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020722.sas 03DEC2020 06:16

Listing 16.2.7.22
Unsolicited Adverse Events – Peripheral Neuropathy
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|---|
| Subject ID: US3012186; Age (years): 73; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Peripheral sensory neuropathy/ WORSENING OF NEUROPATHY SENSORY | 2020-10-02 (15)/ 2020-10-23 (36) | Yes/ Yes/ No | 1 No | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3342205; Age (years): 29; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Peripheral sensory neuropathy/ SENSORY NEUROPATHY LEFT ARM | 2020-09-09 12:00 (2)/ 2020-09-14 08:00 (6) | Yes/ No/ No | 1 No | R/ R | DOSE NOT CHANGED/ CONCOMITANT MEDICATION RECOVERED/ RESOLVED |
| Subject ID: US3622103; Age (years): 55; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Neuralgia/ CERVICAL GANGLIA PAIN | 2020-10-12 (17)/ 2020-10-13 (18) | Yes/ No/ No | 1 No | NR/ NR | NOT APPLICABLE/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020722.sas 03DEC2020 06:16

Listing 16.2.7.22
Unsolicited Adverse Events – Peripheral Neuropathy
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---------------------------|---|---------------------------------------|----------------|
| Subject ID: US3642268; Age (years): 38; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Nervous system disorders/ | 2020-09-21 | Yes/ | 2 No | R/ | DRUG | RECOVERED/ |
| Neuropathy peripheral/ | (1)/ | No/ | | NR | WITHDRAWN/ | RESOLVED |
| NEUROPATHY | 2020-11-04 (45) | No | | | NONE | |
| Subject ID: US3772089; Age (years): 57; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Nervous system disorders/ | 2020-09-18 | Yes/ | 1 No | NR/ | DOSE NOT | RECOVERED/ |
| Neuropathy peripheral/ | (5)/ | No/ | | NR | CHANGED/ | RESOLVED |
| PERIPHERAL NEUROPATHY | 2020-09-25 | No | | | NONE | |
| WORSENING SYMPTOMS | (12) | | | | | |
| Subject ID: US3872197; Age (years): 63; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Nervous system disorders/ | 2020-09-08 | Yes/ | 1 No | NR/ | DOSE NOT | NOT RECOVERED/ |
| Small fibre neuropathy/ | (26)/ | Yes/ | | NA | CHANGED/ | NOT RESOLVED |
| SMALL FIBER MOTOR | Ongoing | No | | | CONCOMITANT | |
| NEUROPATHY BILATERAL | | | | | MEDICATION | |
| LOWER EXTREMITIES | | | | | | |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020722.sas 03DEC2020 06:16

Listing 16.2.7.22
Unsolicited Adverse Events – Peripheral Neuropathy
Safety Set

Peripheral Neuropathy is identified through selected SMQ.
TEAE = Treatment-Emergent Adverse Event; MAAE = Medically-Attended Adverse Event; AR = Adverse Reaction; SAE = Serious Adverse Event; IP = Investigational Product; SP = Study Procedure.
Relative day is defined as days from the most recent injection date.
MedDRA version 23.0.
[1] Sev. = Severity, 1 = Grade 1/Mild, 2 = Grade 2/Moderate, 3 = Grade 3/Severe, 4 = Grade 4.
[2] 1 = Death, 2 = Life threatening, 3 = Requires inpatient or prolongation of existing Hospitalization (Hospital Admission Date/ Hospital Discharge Date), 4 = Persistent or significant disability or incapacity, 5 = Congenital anomaly or birth defect, 6 = Other medically important event.
[3] R = Related, NR = Not Related, NA = Not Applicable.

Listing 16.2.7.23
Unsolicited Adverse Events – Demyelinating Disease of Central Nervous System
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|--|--------------------------------|
| Subject ID: US3502142; Age (years): 45; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Nervous system disorders/ Multiple sclerosis/ MULTIPLE SCLEROSIS | 2020-11-12 (38)/ Ongoing | Yes/ Yes/ No | 4 | Yes/3 (2020-11-12/ 2020-11-13) | NR/ NR CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020723.sas 03DEC2020 06:17

Listing 16.2.7.23
Unsolicited Adverse Events – Demyelinating Disease of Central Nervous System
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|-------------------------|
|--|---|-----------------------------------|---------------------------|--|-------------------------|

There are no observations for this section.

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020723.sas 03DEC2020 06:17

Listing 16.2.7.23
Unsolicited Adverse Events – Demyelinating Disease of Central Nervous System
Safety Set

Demyelinating Disease of Central Nervous System is identified through selected SMQ.

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.24
Unsolicited Adverse Events – Convulsions
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|---------------------------------------|------------|
| Subject ID: US3432183; Age (years): 26; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Nervous system disorders/ | 2020-10-09 | Yes/ | 3 No | NR/ | NOT | RECOVERED/ |
| Seizure/ | (12)/ | Yes/ | | NR | APPLICABLE/ | RESOLVED |
| SEIZURE | 2020-10-09 (12) | No | | | CONCOMITANT PROCEDURE | |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020724.sas 03DEC2020 06:17

Listing 16.2.7.24
Unsolicited Adverse Events – Convulsions
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|----------------------------------|---|--|
| Subject ID: US3462133; Age (years): 61; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Seizure/ GENERALIZED SEIZURES | 2020-08-23 (12)/ 2020-08-26 (15) | Yes/ Yes/ No | 4 (2020-08-23/ 2020-08-26) | NR/ NR CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | DOSE NOT CHANGED/ RESOLVED RECOVERED/ RESOLVED |
| Subject ID: US3542332; Age (years): 56; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Seizure/ EXACERBATION OF SEIZURE DISORDER | 2020-11-07 (30)/ 2020-11-08 (31) | Yes/ Yes/ No | 3 (2020-11-07/ 2020-11-08) | NR/ NR CONCOMITANT MEDICATION | DRUG WITHDRAWN/ RESOLVED RECOVERED/ RESOLVED |
| Subject ID: US3572109; Age (years): 62; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Nervous system disorders/ Seizure/ SEIZURES | 2020-08-28 (2)/ Ongoing | Yes/ Yes/ No | 4 No | NR/ NR NONE | DOSE NOT CHANGED/ NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020724.sas 03DEC2020 06:17

Listing 16.2.7.24
Unsolicited Adverse Events – Convulsions
Safety Set

Convulsions is identified through selected SMQ.

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|----------------------------------|--|------------------------------|--------------------------------|
| Subject ID: US3032277; Age (years): 90; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Gastrointestinal disorders/ Duodenal ulcer haemorrhage/ ACUTE DUODENAL ULCER WITH HEMORRHAGE | 2020-09-12 (24)/ 2020-09-17 (29) | Yes/ Yes/ No | 4 (2020-09-13/ 2020-09-17) | NR/ NR | NOT APPLICABLE/ NONE | RECOVERED/ RESOLVED |
| Subject ID: US3342259; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Infections and infestations/ Pharyngitis/ ACUTE PHARYNGITIS | 2020-09-14 19:00 (1)/ 2020-09-14 20:00 (1) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |
| Nervous system disorders/ Migraine/ MIGRAINE | 2020-09-14 20:00 (1)/ Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|---|--|--|--------------------------------|
| Subject ID: US3342259; Age (years): 41; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Psychiatric disorders/ Depression suicidal/ DEPRESSION WITH SUICIDAL IDEATION | 2020-10-14 (31)/ Ongoing | Yes/ Yes/ No | 3 No | NR/ NR | DRUG WITHDRAWN/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3772051; Age (years): 67; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative General disorders and administration site conditions/ Incarcerated hernia/ ACUTE INCARCERATED VENTRAL HERNIA | 2020-09-04 (24)/ Ongoing | Yes/ Yes/ No | 3 Yes/3 (2020-09-05/ 2020-09-14) | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | NOT RECOVERED/ NOT RESOLVED |
| Renal and urinary disorders/ Acute kidney injury/ ACUTE KIDNEY INJURY | 2020-09-05 (25)/ 2020-09-14 (34) | Yes/ Yes/ No | 3 No | NR/ NR | DOSE DELAYED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|---|---|-----------------------------------|---------------------------|--|--|--------------------------------|
| Subject ID: US3042032; Age (years): 81; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ EXACERBATION OF CHRONIC DYSPNEA | 2020-08-27 (30)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | Negative DRUG WITHDRAWN/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3042192; Age (years): 40; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Investigations/ Hepatic enzyme increased/ ELEVATED LIVER ENZYMES | 2020-08-31 (18)/ Ongoing | Yes/ Yes/ No | 1 No | NR/ NR | Negative DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Infections and infestations/ Sepsis/ SEPSIS | 2020-08-26 (9)/ 2020-08-26 (9) | Yes/ Yes/ No | 2 No | NR/ NR | Negative DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|-------------------------------------|--|--|
| Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Pancreatitis acute/ ACUTE PANCREATITIS | 2020-08-26 (9) / 2020-09-30 (44) | Yes/ Yes/ No | 4 2020-08-26/ 2020-09-30) | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT PROCEDURE |
| Hepatobiliary disorders/ Bile duct stone/ CHOLEDOCHOLITHIASIS | 2020-08-26 (9) / 2020-09-30 (44) | Yes/ Yes/ No | 4 2020-08-26/ 2020-09-30) | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT PROCEDURE |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|-------------------------|
| Subject ID: US3082051; Age (years): 66; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Neoplasms benign, | 2020-08-27 | Yes/ | 2 No | NR/ | DOSE NOT RECOVERED/ |
| malignant and | (10)/ | Yes/ | | NR | CHANGED/ RESOLVED |
| unspecified (incl cysts | 2020-09-30 | No | | | NONE |
| and polyps)/ | (44) | | | | |
| Benign hepatic neoplasm/ RIGHT POSTERIOR BENIGN LIVER LESION | | | | | |
| Subject ID: US3242370; Age (years): 28; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Psychiatric disorders/ | 2020-09-29 | Yes/ | 3 Yes/2/3 | NR/ | DRUG RECOVERED/ |
| Schizoaffective disorder/ | (7)/ | Yes/ | (2020-09-29/ | NR | WITHDRAWN/ RESOLVED |
| WORSENING OF | 2020-10-03 | No | 2020-10-03) | | CONCOMITANT |
| SCHIZOAFFECTIVE DISORDER | (11) | | | | MEDICATION |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [1] | Relation-with IP/ ship to Other Action IP/SP [3] | Action Taken Taken | Outcome |
|--|---|-----------------------------------|----------------------------------|--|--|--------------------------------|
| Subject ID: US3292412; Age (years): 42; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Positive Infections and infestations/ COVID-19/ COVID 19 | 2020-09-25 (2)/ Ongoing | Yes/ Yes/ No | 2 No | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION | NOT RECOVERED/ NOT RESOLVED |
| Subject ID: US3942021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative Psychiatric disorders/ Substance abuse/ POLYSUBSTANCE ABUSE | 2020-09-06 (10)/ Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE | NOT RECOVERED/ NOT RESOLVED |
| Injury, poisoning and procedural complications/ Road traffic accident/ MOTOR VEHICLE ACCIDENT TRAUMA | 2020-09-06 (10)/ 2020-10-01 (35) | Yes/ No/ No | 3 (2020-09-06/ 2020-09-22) | NR/ NR | DRUG WITHDRAWN/ CONCOMITANT MEDICATION, CONCOMITANT PROCEDURE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|---|-----------------------------------|---------------------------|--|-------------------------|
| Subject ID: US3942021; Age (years): 49; Sex: F; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Infections and | 2020-09-13 | Yes/ | 1 No | NR/ | NOT RECOVERED/ |
| infestations/ | (17)/ | No/ | | NR | APPLICABLE/ RESOLVED |
| Urinary tract infection/ | 2020-09-19 | No | | | CONCOMITANT |
| URINARY TRACT INFECTION | (23) | | | | MEDICATION |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020726.sas 03DEC2020 06:17

Listing 16.2.7.26
Unsolicited Adverse Events in Participants Who Discontinued Study due to AE/SAE
Safety Set

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

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

MedDRA version 23.0.

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

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

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

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|-------------------------------|--|---------------------------------------|--------------------------|
| Subject ID: US3032204; Age (years): 54; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Infections and | 2020-11-09 | Yes/ | 4 | Yes/1 | NR/ | FATAL |
| infestations/ | (57)/ | Yes/ | | | NR | |
| COVID-19/ | 2020-11-16 | No | | | | |
| COVID-19 | (64) | | | | CONCOMITANT MEDICATION | |
| Subject ID: US3082269; Age (years): 75; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Cardiac disorders/ | 2020-10-02 | Yes/ | 4 | No | NR/ | NOT RECOVERED/ |
| Atrial fibrillation/ | (12)/ | Yes/ | | | NR | NOT RESOLVED |
| NEW ONSET ATRIAL FIBRILLATION | Ongoing | No | | | NONE | |
| Gastrointestinal disorders/ | 2020-10-02 | Yes/ | 4 | Yes/1/3 | NR/ | FATAL |
| Gastric perforation/ | (12)/ | Yes/ | | (2020-10-02/ | NR | APPLICABLE/ |
| INTRA-ABDOMINAL PERFORATION | 2020-10-03 | No | |) /4/6 | | CONCOMITANT PROCEDURE |
| | (13) | | | | | |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|---|-----------------------------------|---------------------------|--|-------------------------|
| Subject ID: US3082269; Age (years): 75; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Metabolism and nutrition disorders/ | 2020-10-02 (12)/ | Yes/ | 2 No | NR/ | DOSE NOT RECOVERED/ |
| Hyperglycaemia/ | 2020-10-03 (13) | Yes/ | | NR | CHANGED/ RESOLVED |
| HYPERGLYCEMIA | | No | | | NONE |
| Subject ID: US3272070; Age (years): 74; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Cardiac disorders/ | 2020-10-01 (29)/ | Yes/ | 4 Yes/1 | NR/ | NOT FATAL |
| Myocardial infarction/ | | Yes/ | | NR | APPLICABLE/ |
| MYOCARDIAL INFARCTION | 2020-10-01 (29) | No | | | NONE |
| Subject ID: US3322199; Age (years): 64; Sex: M; Race: BLACK OR AFRICAN AMERICAN; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Cardiac disorders/ | 2020-11-16 (47)/ | Yes/ | 4 Yes/1 | NR/ | NOT FATAL |
| Myocardial infarction/ | | Yes/ | | NR | APPLICABLE/ |
| FATAL MYOCARDIAL INFARCTION | 2020-11-16 (47) | No | | | NONE |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|---|--|---|------------------------|
| Subject ID: US3342256; Age (years): 43; Sex: M; Race: UNKNOWN; Baseline SARS-CoV-2 Status: Negative Cardiac disorders/ Cardio-respiratory arrest/ CARDIOPULMONARY ARREST | 2020-09-20 (7) / 2020-09-20 (7) | Yes/ Yes/ No | 4 Yes/1 | NR/ NR | NOT APPLICABLE/ CONCOMITANT MEDICATION | FATAL |
| Subject ID: US3432295; Age (years): 83; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Skin and subcutaneous tissue disorders/ Dermatitis bullous/ DIFFUSE BULLOUS RASH (NON-URTICARIAL) | 2020-09-12 (18) / 2020-10-02 (38) | Yes/ Yes/ No | 4 Yes/1/3 (2020-09-17/ 2020-09-24) | NR/ NR | DOSE DELAYED/ CONCOMITANT MEDICATION | FATAL |
| Blood and lymphatic system disorders/ Lymphadenopathy/ SUPRACLAVICULAR LYMPHADENOPATHY | 2020-09-22 (28) / 2020-10-02 (38) | Yes/ Yes/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: Placebo

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|--|-----------------------------------|---|--|---|---------|
| Subject ID: US3432295; Age (years): 83; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | General disorders and administration site conditions/ 2020-10-01 (37)/ 2020-10-02 (38) | Yes/ Yes/ No | 4 Yes/1/3 (2020-10-01/ 2020-10-02) | NR/ NR | DOSE DELAYED/ CONCOMITANT MEDICATION | FATAL |
| Systemic inflammatory response syndrome/ SEVERE SYSTEMIC INFLAMMATORY SYNDROME IN THE SETTING OF CLL | | | | | | |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|---|--|-----------------------------------|-------------------------------|--|--|
| Subject ID: US3512042; Age (years): 78; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | |
| Gastrointestinal disorders/ Nausea/ NAUSEA | 2020-08-30 (19) / 2020-09-01 (21) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| General disorders and administration site conditions/ Malaise/ MALAISE | 2020-08-30 (19) / 2020-09-01 (21) | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |
| Gastrointestinal disorders/ Vomiting/ VOMITTING X3 | 2020-08-31 (20) / 2020-08-31 (20) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ Criteria [2] | Relation-with IP/ ship to IP/SP [3] | Action Taken Other Action Taken | Outcome |
|--|---|-----------------------------------|---------------------------|---|---------------------------------------|-------------|
| Subject ID: US3512042; Age (years): 78; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Cardiac disorders/ | 2020-09-01 | Yes/ | 4 | Yes/1 | NR/ | FATAL |
| Cardio-respiratory | (21)/ | Yes/ | | | NR | CHANGED/ |
| arrest/ | 2020-09-01 | No | | | NONE | |
| CARDIOPULMONARY ARREST | (21) | | | | | |
| Subject ID: US3752173; Age (years): 77; Sex: M; Race: AMERICAN INDIAN OR ALASKA NATIVE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Cardiac disorders/ | 2020-11-01 | Yes/ | 4 | Yes/1 | NR/ | FATAL |
| Myocardial infarction/ | (45)/ | Yes/ | | | NR | APPLICABLE/ |
| MYOCARDIAL INFARCTION | 2020-11-01 | No | | | NONE | |
| | (45) | | | | | |
| Subject ID: US3872318; Age (years): 62; Sex: M; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Psychiatric disorders/ | 2020-09-16 | Yes/ | 4 | Yes/1 | NR/ | FATAL |
| Completed suicide/ | (21)/ | Yes/ | | | NR | APPLICABLE/ |
| SUICIDE | 2020-09-16 | No | | | NONE | |
| | (21) | | | | | |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day) / End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Outcome |
|--|--|-----------------------------------|-------------------------------|--|---|
| Subject ID: US3962094; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative Investigations/ Blood triglycerides increased/ HIGH TRIGLYCERIDES | 2020-09-12 (4) / Ongoing | Yes/ No/ No | 2 No | NR/ NR | DOSE NOT CHANGED/ CONCOMITANT MEDICATION |
| Gastrointestinal disorders/ Gastrooesophageal reflux disease/ ACID REFLUX | 2020-10-07 (29) / Ongoing | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE |
| Injury, poisoning and procedural complications/ Fall/ FALL | 2020-10-15 (37) / 2020-10-15 (37) | Yes/ No/ No | 1 No | NR/ NR | DOSE NOT CHANGED/ NONE |
| | | | | | RECOVERED/ RESOLVED |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

Treatment Group: mRNA-1273

| System Organ Class/ Preferred Term/ Verbatim | Start Date and Time (Relative Day)/ End Date and Time (Relative Day) | TEAE/ MAAE/ Solicited AR | Sev. SAE/ [1] Criteria [2] | Relation-with IP/ ship to Other Action IP/SP [3] Taken | Action Taken Other Action Taken | Outcome |
|---|---|-----------------------------------|-------------------------------|--|---------------------------------------|---------|
| Subject ID: US3962094; Age (years): 56; Sex: F; Race: WHITE; Baseline SARS-CoV-2 Status: Negative | | | | | | |
| Injury, poisoning and procedural complications/ | 2020-10-15 (37)/ | Yes/ | 4 Yes/1 | NR/ | DOSE NOT | FATAL |
| Head injury/ | 2020-10-15 (37) | No/ | | NR | CHANGED/ | |
| HEAD TRAUMA | | No | | | NONE | |

Note: Footnotes are listed on the last page.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\116020727.sas 03DEC2020 06:17

Listing 16.2.7.27
Unsolicited Adverse Events in Participants Who Died
Safety Set

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

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

MedDRA version 23.0.

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

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

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