

16.2.2 Protocol Deviations

Listing 16.2.2.1 Inclusion and Exclusion Criterion Deviations Subjects Randomized but Did Not Meet Eligibility Criteria

Listing 16.2.2.2 Major Protocol Deviations Randomization Set

Listing 16.2.2.1
Inclusion and Exclusion Criterion Deviations
Subjects Randomized but Did Not Meet Eligibility Criteria

Treatment Group: Placebo

Subject ID	Criterion Type	Description
US3012088	INCLUSION	Healthy adults or adults with pre-existing medical conditions who are in stable condition.
US3052340	INCLUSION	Healthy adults or adults with pre-existing medical conditions who are in stable condition.
US3082013	INCLUSION	Healthy adults or adults with pre-existing medical conditions who are in stable condition.
US3132097	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3162014	EXCLUSION	Has donated >= 450 mL of blood products within 28 days prior to Screening.
US3172054	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3172068	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3172449	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3202340	INCLUSION	Healthy adults or adults with pre-existing medical conditions who are in stable condition.
US3222129	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3322268	INCLUSION INCLUSION	Able to comply with study procedures based on the assessment of the Investigator. Understands and agrees to comply with the study procedures and provides written informed consent.
US3322423	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3382084	EXCLUSION	Demonstrated inability to comply with the study procedures.

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Listing 16.2.2.1
Inclusion and Exclusion Criterion Deviations
Subjects Randomized but Did Not Meet Eligibility Criteria

Treatment Group: Placebo

Subject ID	Criterion Type	Description
US3482115	INCLUSION	Healthy adults or adults with pre-existing medical conditions who are in stable condition.
US3512243	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3562206	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3762002	EXCLUSION	Has received or plans to receive a non-study vaccine within 28 days before/after any dose of IP (except for seasonal influenza vaccine which not permitted within 14 days before/after any dose of IP).
US3792041	EXCLUSION	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids = 20 mg/day of prednisone equivalent).
US3802086	INCLUSION	
US3802101	EXCLUSION	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids = 20 mg/day of prednisone equivalent).
US3802222	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.

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Listing 16.2.2.1
Inclusion and Exclusion Criterion Deviations
Subjects Randomized but Did Not Meet Eligibility Criteria

Treatment Group: mRNA-1273

Subject ID	Criterion Type	Description
US3102403	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3162042	EXCLUSION	Has donated >= 450 mL of blood products within 28 days prior to Screening.
US3172125	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3172214	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3172235	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3202365	EXCLUSION	Demonstrated inability to comply with the study procedures.
US3372432	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3482308	EXCLUSION	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids = 20 mg/day of prednisone equivalent).
US3562234	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3642173	EXCLUSION	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids = 20 mg/day of prednisone equivalent).

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Listing 16.2.2.1
Inclusion and Exclusion Criterion Deviations
Subjects Randomized but Did Not Meet Eligibility Criteria

Treatment Group: mRNA-1273

Subject ID	Criterion Type	Description
US3692054	EXCLUSION	Immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (HIVpositive participants with CD4 count =350 cells/mm3 and an undetectable HIV viral load within the past year).
US3722418	EXCLUSION	Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids = 20 mg/day of prednisone equivalent).
US3762016	EXCLUSION	Has received systemic immunosuppressants/immune-modifying drugs for >14 days in total within 6 months prior to Screening. Topical tacrolimus is allowed if not used within 14 days prior to Screening.
US3802176	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3902113	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3902114	INCLUSION	Understands and agrees to comply with the study procedures and provides written informed consent.
US3902131	INCLUSION	Able to comply with study procedures based on the assessment of the Investigator.
US3942107	EXCLUSION	Demonstrated inability to comply with the study procedures.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002001	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-07 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002004	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-13 (110)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3002008	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002013	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002015	2020-08-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3002020	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002026	2020-08-26 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002029	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002031	2020-11-23 (119)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002034	2020-08-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3002049	2020-09-17 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002074	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3002075	2020-08-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002076	2020-11-18 (111)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-02-24 (209)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002078	2020-07-30 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3002079	2020-11-25 (118)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-03-17 (230)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002094	2020-09-17 (45)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002100	2020-09-03 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002108	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002133	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002136	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002153	2020-10-26 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002159	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3002165	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-19 (159)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3002166	2021-02-02 (170)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-01 (197)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002168	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002176	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3002178	2020-09-24 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002183	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002202	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002203	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002204	2020-08-28 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3002216	2021-02-22 (176)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002231	2020-10-02 (31)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002231	2020-10-02 (31)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3002235	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3002236	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002237	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002240	2020-11-09 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002242	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3002247	2020-10-04 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002260	2020-12-02 (86)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-04 (88)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3002265	2020-10-12 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002269	2020-09-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3002270	2020-10-09 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3002273	2021-02-25 (170)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-26 (199)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002279	2020-10-10 (31)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002288	2020-12-18 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002290	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-13 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3002294	2020-10-09 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002299	2020-12-05 (86)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
	2020-12-07 (88)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3002307	2020-10-23 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002312	2020-10-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002317	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3002319	2020-12-08 (76)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3002322	2020-10-23 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3002325	2020-12-08 (76)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3002326	2020-10-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002334	2021-03-01 (154)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-03-09 (162)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3002339	2020-10-02 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002341	2020-11-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002356	2020-10-11 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-06 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-07 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002360	2020-11-11 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-16 (156)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002366	2020-10-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-16 (62)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-17 (63)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002369	2020-11-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3012002	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-21 (26)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-05 (163)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012003	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012005	2020-08-18 (23)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012005	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012008	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012014	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012015	2020-07-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012017	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012018	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012018	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012022	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012024	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-26 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012025	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012027	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012028	2020-08-26 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-08-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012028	2020-12-30 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3012029	2020-08-26 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-12-19 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012031	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012040	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012041	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012043	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-25 (57)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3012044	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012047	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012051	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012052	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012055	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012057	2020-09-04 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012060	2020-09-24 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012060	2020-09-24 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3012061	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012062	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (35)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012063	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012065	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-06 (154)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012066	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012072	2020-09-04 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012072	2020-12-20 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012073	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012076	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012077	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012078	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-12-21 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012079	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012080	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012081	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012082	2020-08-15 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-08 (33)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012085	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012088	2020-08-10 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3012114	2021-01-01 (144)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-20 (163)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3012137	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-10 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3012138	2020-08-28 (15)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012143	2020-08-13 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3012154	2020-10-01 (49)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-08 (56)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3012157	2020-08-17 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3012164	2020-10-21 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3012175	2020-08-17 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3012179	2020-12-05 (109)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3012181	2020-09-23 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012194	2020-08-31 (12)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-28 (131)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012195	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3012203	2020-12-26 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012206	2020-08-28 (8)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3012212	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-26 (3)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3012222	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012222	2021-03-11 (200)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3012229	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3012230	2020-08-28 (3)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-12-30 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012239	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3012241	2020-08-28 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012241	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3012244	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3012265	2020-10-28 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3012275	2020-12-17 (105)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012276	2021-02-21 (171)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3012300	2021-03-08 (176)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3012328	2020-10-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (95)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012329	2021-01-23 (131)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3012334	2021-01-11 (89)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-17 (95)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3012350	2020-10-27 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3022004	2020-10-13 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022005	2020-07-28 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
	2020-09-01 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3022014	2020-08-27 (32)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-04 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-30 (127)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022023	2020-08-27 (32)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-10 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022024	2020-09-02 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022025	2020-09-05 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022026	2020-09-25 (61)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022035	2020-10-07 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-05 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022036	2020-09-18 (53)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022053	2020-07-27 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3022054	2020-11-05 (101)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022058	2020-09-04 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3022065	2020-08-06 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3022066	2021-01-06 (162)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3022070	2020-09-11 (45)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3022071	2020-08-03 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022071	2020-08-22 (25)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-09 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-29 (63)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3022076	2020-09-07 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-08 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022082	2020-09-10 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022083	2020-09-10 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022084	2020-09-10 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022085	2020-09-28 (61)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022097	2020-10-07 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022111	2020-11-25 (115)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-02 (122)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-26 (146)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3022119	2020-09-24 (51)	ICF Process/Timing	I02.01: Signed informed consent not available on site
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022132	2020-09-08 (30)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-11-16 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022134	2020-09-08 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022137	2020-08-15 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-10 (32)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-15 (67)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3022139	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-13 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022145	2020-08-15 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3022156	2020-09-24 (39)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022171	2020-08-22 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022178	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-30 (104)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3022179	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-21 (3)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-17 (91)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022181	2020-09-24 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022184	2020-08-22 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022186	2021-01-14 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3022201	2020-11-30 (103)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022211	2020-10-07 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-21 (124)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-03-12 (205)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3022223	2020-11-23 (96)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-11-24 (97)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-02 (105)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-22 (125)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3022226	2020-11-30 (103)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022226	2021-01-19 (153)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3022229	2020-10-09 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022233	2020-11-16 (89)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022236	2021-03-13 (206)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3022239	2021-01-20 (154)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3022241	2020-11-30 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022243	2020-09-29 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-02 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022251	2020-09-29 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022264	2020-11-30 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022285	2020-10-01 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-30 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022291	2020-11-20 (89)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3022295	2020-08-28 (3)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3022303	2020-09-08 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022303	2020-11-19 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022313	2020-11-12 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022317	2020-09-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-30 (70)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022319	2020-11-30 (70)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3022320	2020-09-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3032006	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3032022	2020-08-03 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3032035	2020-11-25 (120)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032046	2020-07-29 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-19 (82)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3032047	2021-03-02 (216)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032048	2020-09-03 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032081	2020-08-08 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3032095	2020-11-13 (101)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-11 (219)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032109	2020-12-04 (122)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3032112	2021-01-22 (171)	Inv Safety Rptg (Reg/Sponsor)	I12.02: Pregnancy not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032113	2020-09-29 (55)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3032123	2020-11-17 (104)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3032136	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032139	2020-11-10 (96)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032143	2020-12-15 (131)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3032146	2020-09-16 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-15 (221)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032153	2020-08-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032158	2021-03-12 (217)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032159	2020-09-11 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3032161	2020-08-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3032171	2020-09-08 (30)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3032172	2020-09-01 (23)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-09-21 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032185	2020-09-09 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3032225	2021-02-03 (169)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3032227	2021-03-19 (213)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032234	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3032236	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032240	2020-10-20 (63)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3032241	2021-01-05 (140)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3032242	2021-02-08 (174)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3032248	2021-03-17 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032263	2020-12-08 (111)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032263	2020-12-09 (112)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-09 (143)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3032265	2021-02-25 (190)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3032266	2021-03-23 (216)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032270	2020-09-18 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-19 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032275	2021-03-11 (204)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3032277	2020-10-01 (43)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032278	2021-01-07 (141)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3032310	2020-09-22 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032320	2021-01-07 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3032329	2021-02-05 (168)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3032339	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3032341	2020-09-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032345	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032349	2020-11-16 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042006	2020-07-27 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042008	2020-07-27 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042011	2020-07-27 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-12 (108)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042015	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042018	2020-08-29 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042025	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042026	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-21 (85)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3042028	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042035	2020-10-05 (68)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-09 (72)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042036	2020-07-29 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042037	2020-07-29 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042041	2020-09-03 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3042043	2020-12-21 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042047	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042049	2020-09-05 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042051	2020-08-31 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-02-12 (194)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042052	2020-09-08 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042062	2020-09-14 (42)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042063	2020-08-17 (14)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-09-01 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3042078	2020-08-07 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-09 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-15 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042080	2020-09-04 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042083	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-16 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3042091	2020-09-29 (55)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042091	2020-09-29 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042095	2020-11-17 (104)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042102	2021-01-04 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042106	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-30 (177)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042113	2021-01-04 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042114	2020-08-12 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-06 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042115	2020-11-24 (110)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042126	2020-10-14 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042134	2020-09-23 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-25 (46)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042136	2020-09-12 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042144	2020-11-18 (100)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042146	2020-09-18 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042152	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042153	2020-11-12 (93)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042189	2020-09-21 (40)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3042197	2021-01-11 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042209	2020-09-16 (34)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3042220	2021-01-11 (148)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042228	2020-08-18	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042230	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042231	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042241	2020-12-25 (129)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-30 (134)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042244	2020-11-12 (86)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3042252	2020-10-27 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042253	2020-10-27 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042288	2020-12-02 (104)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-04 (106)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042288	2020-12-06 (108)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-09 (111)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-21 (123)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-28 (130)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3042294	2020-09-28 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042304	2020-08-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052001	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052004	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052006	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052006	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052009	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052011	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-26 (212)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052012	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052012	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-01 (34)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-02 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052016	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052019	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052020	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052022	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-28 (183)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052022	2021-01-28 (183)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052023	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-02 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052024	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-08-25 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052029	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-23 (56)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052030	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-03 (36)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052031	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052033	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052037	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-05 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052038	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052040	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052042	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052044	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052045	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3052047	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (26)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-02 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052049	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052051	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-27 (89)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052053	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052054	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052055	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052060	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052062	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052068	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-03 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052069	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-07 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052075	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-04 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052076	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052079	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052080	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052080	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052081	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-10 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052083	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052084	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052085	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052085	2020-09-03 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3052088	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052090	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052092	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052098	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-08 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052099	2020-08-03 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052099	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-08 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052101	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-27 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052103	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-22 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3052109	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052112	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052112	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-11 (37)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3052113	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052115	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-11-23 (110)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3052116	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052117	2020-08-06 (1)	ICF Process/Timing Study Treatment Randomization	I02.04: Informed consent not signed and/or dated by appropriate site staff P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-13 (161)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052117	2021-01-13 (161)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052119	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052122	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-14 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052123	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052125	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052126	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (36)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052133	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-11 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052134	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052136	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-09 (95)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052138	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052141	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-14 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052144	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052146	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-08-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052151	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052152	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-24 (46)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052152	2020-09-24 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052154	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052155	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052156	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-18 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052157	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052160	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052165	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052168	2020-08-11 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052170	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052174	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052176	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052177	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052179	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052180	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052183	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052187	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052188	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-09 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-10 (210)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052189	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052192	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052194	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052195	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052197	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052200	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052202	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052203	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-08-26 (14)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-12 (61)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-14 (124)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052204	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052205	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052209	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-25 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052211	2020-08-13 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052214	2020-08-13 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052220	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052221	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052222	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052223	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052226	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052227	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-11 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-04 (203)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052230	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052231	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052232	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-02-26 (197)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052234	2020-09-17 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052240	2020-10-26 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052245	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-17 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052255	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052261	2021-03-10 (205)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052263	2020-11-10 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052264	2020-08-14 (-5)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052265	2020-08-14 (-5)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-27 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-15 (209)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052270	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-27 (70)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052272	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-15 (28)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052280	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-10 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052284	2020-11-04 (76)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052294	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052296	2020-12-10 (109)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052303	2020-09-18 (26)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-10-08 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052305	2020-09-18 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052306	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052312	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052314	2020-09-30 (34)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-03-03 (188)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052315	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052316	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052317	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052320	2020-10-21 (55)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052323	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-09 (194)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052329	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-11-04 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052334	2020-11-10 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052340	2020-08-31	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
	2020-09-01	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052349	2021-01-16 (137)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052353	2020-11-13 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052357	2020-10-06 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-13 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052358	2020-11-10 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052360	2020-09-03 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-05 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052366	2020-09-20 (18)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
	2020-10-05 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-12 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052369	2020-10-06 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052370	2020-10-06 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052372	2020-10-08 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052372	2020-12-21 (110)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052374	2020-10-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-15 (193)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3052379	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-14 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-19 (197)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052380	2020-09-08 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-08 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3062003	2021-01-19 (173)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062003	2021-01-31 (185)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062009	2020-08-03 (4)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-08-10 (11)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-08-12 (13)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3062015	2020-09-15 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-28 (182)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-09 (222)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3062022	2020-08-12 (12)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062022	2020-08-12 (12)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-08-14 (14)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-10-21 (82)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-27 (119)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062026	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3062053	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062062	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3062087	2021-02-19 (200)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3062089	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-19 (137)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-24 (142)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-31 (149)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062102	2021-02-26 (206)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-28 (208)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062123	2020-09-05 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062124	2021-01-29 (177)	Study Procedures/Assessments	P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3062131	2020-11-07 (94)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062135	2020-12-24 (141)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062165	2021-01-08 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3062167	2021-02-04 (181)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062172	2020-10-15 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3062185	2020-08-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3062200	2020-09-11 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062204	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3062210	2021-01-11 (154)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3062223	2020-09-11 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3062231	2020-09-11 (29)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
US3062232	2020-09-11 (29)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
US3062236	2020-09-11 (29)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3062267	2021-01-29 (168)	Study Procedures/Assessments	P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062268	2021-01-29 (168)	Study Procedures/Assessments	P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3062269	2020-08-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3062271	2020-09-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3062275	2020-09-18 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3062296	2021-01-29 (149)	Study Procedures/Assessments	P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3062307	2020-11-24 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-29 (142)	Study Procedures/Assessments	P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
	2021-02-25 (169)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062307	2021-02-27 (171)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-01 (173)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062311	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-21 (41)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3082004	2021-01-13 (161)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082013	2020-08-28	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3082015	2020-08-10 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-20 (163)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082015	2021-01-20 (163)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-18 (220)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082019	2020-12-28 (139)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3082021	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3082029	2021-01-04 (144)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082034	2020-08-12 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082043	2020-08-16 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-10 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082054	2020-08-12 (-6)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3082066	2020-08-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3082068	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-23 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3082076	2020-12-21 (124)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082083	2021-01-20 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082083	2021-01-20 (153)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-18 (210)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082091	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082093	2020-10-01 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3082102	2021-03-18 (206)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082107	2020-12-21 (119)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082115	2020-10-12 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082116	2021-01-25 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082116	2021-01-25 (153)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-26 (154)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-02-19 (178)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082128	2021-01-29 (156)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082131	2020-12-21 (116)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082133	2020-12-30 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082136	2021-01-07 (133)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082141	2020-12-28 (120)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-18 (200)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082152	2020-10-01 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-21 (115)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082154	2020-08-30 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-22 (176)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-18 (200)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082165	2020-12-30 (122)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082165	2021-02-27 (181)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3082166	2020-10-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3082167	2021-01-05 (119)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082174	2020-11-09 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082176	2020-11-09 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082179	2020-12-30 (120)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082198	2020-12-21 (109)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082201	2020-12-21 (109)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082241	2020-12-11 (88)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3082247	2020-11-18 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082249	2021-01-28 (135)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-18 (184)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082260	2020-11-19 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082261	2020-10-24 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3082264	2020-09-24 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3082266	2020-11-20 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092001	2020-12-14 (133)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3092006	2020-10-16 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092015	2020-09-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092016	2020-11-11 (100)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092019	2020-10-13 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (113)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092019	2020-11-30 (118)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-07 (125)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3092026	2020-11-10 (98)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-02 (120)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-23 (141)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-01-21 (170)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-25 (205)	Missing Endpoint Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days P07.07: Saliva sample not collected when required per protocol
US3092034	2020-09-25 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092034	2020-10-01 (57)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092037	2020-09-03 (29)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
	2021-02-26 (205)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3092040	2020-10-13 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-29 (177)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-24 (203)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092041	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-27 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3092045	2020-08-08 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092047	2020-09-14 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-11 (98)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092049	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092051	2020-08-13 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-13 (68)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092054	2020-09-17 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-06 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-06 (212)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092059	2020-10-12 (67)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092065	2020-11-25 (111)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092065	2020-12-06 (122)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-08 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-15 (131)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3092071	2021-02-26 (203)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3092072	2020-08-08 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-08 (62)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-03-11 (216)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092075	2021-01-13 (159)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3092076	2020-11-11 (96)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092078	2020-10-08 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092080	2020-09-14 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092085	2021-01-01 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3092087	2020-09-22 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092088	2020-09-21 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-26 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092089	2020-09-16 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092092	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092094	2020-12-30 (143)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092098	2020-09-16 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-10 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092101	2020-09-18 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-28 (140)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-11 (213)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-23 (225)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092103	2020-09-23 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092105	2020-09-29 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092106	2020-09-23 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-26 (47)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092109	2020-09-15 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092114	2020-08-17 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-16 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-18 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092120	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-10 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092123	2020-10-12 (62)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092125	2021-02-24 (197)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092129	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092134	2020-09-23 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-20 (159)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-27 (166)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-08 (178)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-23 (193)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-26 (196)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-02 (200)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-03-03 (201)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092136	2020-10-20 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092142	2020-09-15 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092148	2020-10-26 (73)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092148	2020-10-27 (74)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092154	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3092156	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3092163	2020-12-22 (126)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-27 (162)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3092165	2020-10-12 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-24 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3092168	2020-09-25 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092169	2020-11-19 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092183	2021-03-01 (193)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092190	2020-10-09 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092193	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-25 (94)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3092198	2020-10-13 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092200	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092201	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092201	2020-09-29 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092202	2020-10-08 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092204	2020-10-16 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092205	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-07 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092209	2020-10-02 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092210	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092211	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092212	2020-08-24 (-1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-11 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092215	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3092222	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-28 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092223	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092228	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092229	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092231	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092245	2020-10-03 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092256	2020-10-06 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-28 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092272	2021-01-11 (136)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-19 (144)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-27 (152)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092274	2020-10-09 (42)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3092277	2020-12-14 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3092287	2020-09-30 (29) 2021-03-26 (206)	Study Treatment Admin/Dispense Study Procedures/Assessments	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3092301	2020-10-12 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092305	2020-10-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092306	2020-12-24 (105)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092307	2020-10-15 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102001	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102003	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102006	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102007	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102009	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102012	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102018	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-18 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102026	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102027	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102029	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102041	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-07 (163)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102042	2021-02-20 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102043	2020-07-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102044	2020-07-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102046	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-08 (195)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102050	2020-07-29	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102056	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102058	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-06 (130)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3102060	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102065	2021-03-19 (233)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102071	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-20 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3102073	2020-12-12 (132)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-02-23 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102077	2021-01-07 (158)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102079	2021-02-23 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102081	2020-12-10 (130)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-12 (132)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102090	2020-12-23 (143)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102091	2020-07-28 (-6)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-03 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3102095	2021-02-26 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102098	2021-02-26 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102103	2021-01-22 (172)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102108	2020-10-01 (59)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-02-27 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102110	2020-10-12 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3102119	2021-02-28 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102121	2021-02-28 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102129	2021-02-28 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102130	2020-08-05 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102135	2021-03-01 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102139	2021-03-01 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102140	2021-03-03 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102145	2021-03-02 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102146	2020-10-08 (60)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-02 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102147	2021-03-02 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102151	2021-03-08 (211)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102153	2020-08-05 (-5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-17 (220)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102158	2021-03-09 (212)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102162	2020-08-09 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3102167	2021-03-09 (211)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102172	2021-01-13 (156)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102180	2020-08-10 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-13 (156)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102181	2020-08-10 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102182	2021-01-14 (157)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102184	2021-03-06 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102186	2020-11-27 (108)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102189	2021-03-07 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102190	2021-03-07 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102191	2021-03-07 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102193	2021-02-15 (188)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102198	2021-03-25 (224)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102207	2021-03-13 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102209	2021-02-18 (185)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102213	2021-03-12 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102218	2021-03-12 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102221	2021-03-13 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102224	2021-03-13 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102226	2020-08-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102235	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-19 (122)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102237	2021-03-14 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102238	2021-03-13 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102243	2021-03-15 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102250	2021-03-15 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102251	2020-11-08 (80)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-03-16 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102253	2021-03-16 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102259	2021-03-14 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102266	2020-09-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102267	2020-12-23 (120)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102269	2021-03-23 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102271	2021-02-20 (179)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3102272	2021-03-20 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102276	2021-01-01 (128)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-01-11 (138)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-13 (140)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3102278	2020-12-31 (127)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102283	2020-07-27 (-31)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-16 (82)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102283	2020-11-25 (91)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-31 (127)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102285	2021-02-10 (167)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102287	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102288	2021-03-21 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102290	2021-03-23 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102292	2021-03-23 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102303	2020-09-25 (25)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102310	2020-12-22 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102316	2020-09-25 (23)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102317	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-25 (23)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3102343	2020-11-20 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3102344	2020-11-20 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3102348	2021-02-12 (154)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102353	2021-01-07 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102356	2020-09-13 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3102361	2020-11-27 (75)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2020-12-05 (83)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-12-14 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3102363	2021-02-20 (159)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102365	2021-01-30 (138)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3102379	2021-02-28 (164)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102381	2021-01-01 (106)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-01-13 (118)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102388	2020-09-13 (-5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-28 (133)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102394	2020-09-13 (-11)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3102401	2020-12-21 (85)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102409	2021-03-25 (172)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3112002	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3112003	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112010	2020-07-29 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3112049	2020-12-29 (152)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112051	2020-08-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112054	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3112055	2020-08-06 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112062	2020-09-02 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112066	2020-08-03 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3112069	2020-10-07 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112076	2021-01-01 (151)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3112077	2021-01-01 (151)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3112080	2020-09-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112087	2021-03-24 (233)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error
US3112106	2021-01-28 (177)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112114	2020-09-08 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112117	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3112118	2020-08-05	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112119	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3112127	2020-09-06 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112132	2021-03-17 (224)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112134	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112135	2020-10-06 (62)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112149	2021-01-06 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3112154	2020-09-14 (39)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3112162	2020-08-28 (19)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112164	2020-10-28 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112173	2020-09-10 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3112179	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-19 (163)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3112185	2021-03-04 (206)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3112190	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112195	2020-08-16 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112203	2020-09-14 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112211	2021-01-01 (143)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-02 (144)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-08 (150)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3112219	2020-12-25 (136)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3112221	2021-02-09 (182)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3112223	2020-09-22 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-23 (42)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-26 (45)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-14 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3112233	2020-09-21 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112234	2020-08-18 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112247	2020-10-21 (70)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3112250	2021-03-26 (225)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112259	2020-08-14 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
	2020-09-15 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-24 (223)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error
US3112262	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-26 (197)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112274	2020-10-22 (67)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112290	2020-10-22 (66)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112293	2021-03-11 (206)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112299	2020-09-28 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112300	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112303	2020-08-23 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112308	2020-08-31 (14)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112309	2020-08-18 (1)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112318	2020-08-22 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112327	2020-10-29 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112337	2020-08-20 (1)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3112353	2020-08-21 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3112366	2020-10-10 (48)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3112367	2020-09-27 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112393	2020-10-02 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112405	2020-08-31 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112405	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112413	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-29 (34)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-17 (144)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-25 (152)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3112419	2020-08-29 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-29 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112444	2020-08-24 (-9)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3112450	2020-09-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3112454	2020-11-16 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112460	2020-10-26 (48)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112469	2020-10-15 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-10 (153)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3112475	2020-12-19 (96)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-20 (97)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-21 (98)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-22 (99)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-23 (100)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-30 (107)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112475	2020-12-30 (107)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3112479	2020-10-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112480	2020-12-11 (87)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3112486	2020-10-15 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122003	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122004	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122006	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-06 (11)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122011	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122012	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122013	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122018	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122023	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122025	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122026	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-06 (11)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122030	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122031	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-26 (31)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122031	2020-12-09 (136)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3122032	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-18 (115)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-20 (117)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-22 (119)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-24 (121)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-25 (122)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122032	2020-11-29 (126)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-06 (133)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3122033	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122035	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-06 (11)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-09-14 (50)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3122036	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122036	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122037	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-03 (8)	Missing Endpoint Assessments	P07.02: Low serum volume collected (not sufficient to perform testing)
	2020-08-25 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-26 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (82)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122039	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-03 (8)	Missing Endpoint Assessments	P07.02: Low serum volume collected (not sufficient to perform testing)
US3122040	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122042	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122043	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122048	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122049	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122050	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122052	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122055	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-18 (144)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3122058	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122059	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-07 (103)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-11 (107)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3122061	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-11 (227)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122067	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122068	2020-07-27 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-26 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3122069	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-29 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-16 (51)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122069	2020-09-17 (52)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122070	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122074	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122076	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-10 (198)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3122078	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122081	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122083	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122084	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-07-29 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122085	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122088	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-16 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3122102	2021-03-11 (226)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3122103	2020-07-29 (1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122105	2021-01-13 (169)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3122106	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-11 (167)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3122107	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122109	2020-07-27 (-2)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (80)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122110	2020-07-29 (1)	Missing Endpoint Assessments	P07.02: Low serum volume collected (not sufficient to perform testing)
	2020-10-07 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122116	2020-08-25 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122119	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122123	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3122126	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122127	2020-08-25 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3122129	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122143	2020-09-02 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122143	2020-09-30 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122148	2020-10-27 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3132001	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3132002	2020-09-02 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3132003	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3132005	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-08 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132017	2020-12-18 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3132018	2020-09-14 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-23 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-13 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3132027	2020-10-15 (51)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-23 (90)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-26 (93)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-13 (110)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132027	2020-12-30 (127)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3132029	2020-09-21 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3132030	2020-08-27 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-12-29 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3132035	2020-10-12 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3132039	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-19 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132039	2021-01-22 (142)	Withdrawal/Term Criteria	P11.01: Anytime withdrawal criteria are met but subject was not withdrawn
US3132043	2020-10-14 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-30 (112)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-05 (118)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-02-03 (147)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-02-16 (160)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3132046	2021-01-22 (131)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132046	2021-01-28 (137)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3132047	2020-11-10 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-12-23 (101)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3132053	2020-12-23 (100)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3132057	2020-12-22 (98)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3132067	2020-10-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132071	2020-10-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-04 (110)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3132078	2020-11-13 (54)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-01 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-15 (86)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-23 (94)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-26 (97)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-30 (101)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132081	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3132084	2020-10-19 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-03 (134)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-10 (141)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-02-26 (157)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3132092	2020-11-03 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3132097	2020-10-01	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3132107	2020-10-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132110	2021-03-05 (149)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3132114	2020-12-17 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3132125	2020-10-15	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3132129	2020-10-16 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3132134	2021-01-05 (79)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3132135	2020-12-18 (61)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-12-31 (74)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3132138	2020-11-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3132140	2020-10-20	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132140	2020-10-20	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3132141	2020-11-23 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3132142	2020-12-23 (65)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3132152	2020-10-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142002	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142003	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142004	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142005	2020-08-27 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142006	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-28 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142007	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-19 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142011	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-04 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-20 (175)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142013	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (62)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142013	2020-10-04 (67)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-06 (100)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3142014	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142015	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-14 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142020	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142023	2020-07-30 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-01 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142025	2020-11-12 (105)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142027	2020-08-27 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-01 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142034	2020-12-14 (137)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-17 (140)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3142037	2020-12-02 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142040	2020-08-30 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142043	2020-09-01 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142045	2020-08-28 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142046	2020-08-28 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142047	2020-08-28 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-02 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142049	2020-08-30 (30)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-08-31 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-12 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142050	2020-09-02 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-12 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142052	2020-09-01 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142053	2020-09-01 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142053	2021-01-07 (158)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142055	2021-01-18 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142056	2020-09-01 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-03-26 (236)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3142061	2020-09-01 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142062	2020-09-01 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-21 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142066	2020-09-05 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-09 (129)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142067	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142070	2020-09-08 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2021-01-28 (179)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142072	2020-08-31 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142073	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142077	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142078	2020-08-31 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-25 (176)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-22 (204)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3142086	2021-01-18 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142088	2020-09-01 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3142089	2020-09-01 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3142092	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142096	2020-08-31 (28)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-09-07 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142097	2020-09-23 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-24 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-21 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142100	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-27 (55)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142102	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142104	2020-11-04 (92)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3142107	2020-09-08 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-13 (161)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142111	2020-09-08 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3142115	2020-09-03 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142116	2020-09-11 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-16 (134)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142120	2020-09-08 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3142122	2020-09-02 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3142126	2020-09-08 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-11 (218)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142127	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142128	2020-09-04 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-22 (201)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142133	2020-09-08 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142135	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142136	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142137	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142139	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-28 (176)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.01: Subject was not observed for at least 30 minutes after vaccination
US3142140	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142142	2020-09-08 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142143	2020-11-11 (98)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-20 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142144	2020-09-09 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-25 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142145	2021-02-25 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142148	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142150	2020-09-02 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142154	2020-09-02 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-13 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142155	2020-09-02 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (33)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142155	2020-09-08 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142158	2021-01-25 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142159	2020-09-08 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-09 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142161	2020-09-02 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-11 (188)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-24 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142168	2020-09-15 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-19 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142170	2021-01-11 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142172	2020-09-09 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142174	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142177	2021-01-25 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142180	2020-09-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142188	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-21 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-11 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142190	2020-09-14 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142191	2020-09-14 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142191	2020-09-15 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142195	2020-09-02 (23)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3142197	2020-09-08 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142200	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142201	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-21 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-20 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142204	2020-08-15 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (44)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142204	2020-09-24 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142205	2020-09-21 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3142212	2020-09-02 (21)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-05 (146)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142214	2020-09-18 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142215	2020-08-20 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3142216	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3142218	2020-09-17 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142221	2021-01-27 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142222	2020-09-21 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-02-15 (186)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3142225	2021-01-14 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142226	2020-09-29 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-02 (108)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142228	2020-08-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-05 (142)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-08 (145)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3142232	2020-09-16 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142232	2020-12-06 (111)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-05 (141)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3142234	2021-03-08 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142236	2020-09-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142240	2021-01-20 (155)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142241	2021-01-28 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142244	2020-09-02 (15)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3142246	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-27 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142249	2021-02-01 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142250	2020-10-05 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-12 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142252	2020-11-11 (79)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3142255	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
			P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142256	2020-10-05 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142256	2020-10-05 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142259	2021-02-28 (187)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142260	2021-01-28 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142262	2021-01-28 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142266	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-28 (55)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-02 (90)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-16 (166)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142267	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142267	2021-02-08 (158)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-17 (195)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142273	2021-02-04 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142274	2021-01-12 (114)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142275	2021-01-25 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142276	2021-02-16 (140)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3152025	2020-08-25 (28)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3152033	2020-09-14 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3152034	2020-08-07 (10)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-11-10 (105)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152038	2020-10-07 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152051	2020-09-03 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152056	2020-07-31 (2)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152065	2020-12-29 (152)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3152082	2020-09-24 (52)	Missing Endpoint Assessments Study Treatment Admin/Dispense Visit Scheduling	P07.06: Nasopharyngeal swab sample not collected when required per protocol P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3152083	2020-09-06 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152088	2020-09-05 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152088	2020-12-03 (121)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3152090	2020-08-12 (1)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
US3152103	2020-08-27 (22)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152105	2021-01-24 (172)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-04 (211)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3152107	2020-09-05 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-27 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152117	2020-12-25 (141)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3152118	2020-08-14 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152118	2020-10-21 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152119	2020-10-13 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152146	2020-09-14 (34)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152156	2020-09-17 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152164	2020-09-19 (38)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152178	2020-09-14 (33)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-15 (187)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3152189	2020-09-19 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152190	2020-08-31 (18)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152207	2021-01-25 (165)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-02-12 (183)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-03-16 (215)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152213	2020-10-28 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152223	2021-01-07 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-28 (168)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3152226	2020-12-29 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3152227	2020-10-09 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152228	2020-09-20 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152239	2020-09-24 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152244	2020-12-18 (126)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152250	2020-10-02 (49)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152259	2020-10-26 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-02 (80)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3152271	2021-01-20 (159)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3152283	2020-09-28 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152297	2020-12-24 (129)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152302	2020-09-24 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152304	2020-08-20 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3152309	2020-10-16 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152319	2020-09-22 (34)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3152320	2020-09-22 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152328	2020-09-25 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152334	2020-09-25 (37)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152348	2020-12-29 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3152349	2020-09-23 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152357	2020-11-16 (88)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152367	2020-10-01 (42)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152381	2020-09-16 (26)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-25 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152402	2020-10-22 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152405	2020-10-17 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152410	2020-09-28 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152412	2020-11-02 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-13 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3152414	2020-10-13 (15)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152426	2020-10-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-05 (155)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152436	2020-11-09 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152462	2020-11-13 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152468	2020-11-16 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152473	2020-10-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152475	2020-11-18 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152506	2020-10-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3152512	2020-12-17 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152516	2020-10-20 (-1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3152522	2021-01-17 (89)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3152523	2021-01-05 (77)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3152544	2020-10-24 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (8)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162001	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-01 (190)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3162004	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3162006	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-30 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-08 (44)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-02-19 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162010	2021-02-20 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162012	2020-08-04 (8)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162014	2020-07-29 (-12)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3162020	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162027	2020-07-29 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162030	2021-02-22 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162032	2020-07-30 (1)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-23 (86)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3162035	2021-01-07 (161)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (237)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162035	2021-03-24 (237)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162045	2020-08-04 (2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162046	2020-08-04 (2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162047	2020-09-08 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-26 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162057	2021-02-28 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162059	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162063	2020-09-08 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162065	2021-03-01 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-02 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-24 (231)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162068	2021-03-17 (224)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162072	2021-03-01 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162075	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162076	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162077	2020-08-11 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3162079	2020-09-06 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162090	2020-08-10 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3162097	2021-03-06 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162113	2020-09-01 (20)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-09-08 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-24 (224)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3162116	2021-01-26 (167)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3162120	2020-12-22 (132)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (224)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162121	2021-03-26 (226)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3162124	2021-03-16 (215)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162128	2021-03-12 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162137	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162149	2020-09-08 (21)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-04 (108)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162155	2020-09-18 (30)	Accidental Unblinding	P12.01: Inadvertent unblinding of site personnel
US3162159	2020-09-16 (28)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162163	2021-01-13 (147)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3162165	2021-03-24 (217)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162185	2020-12-16 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
		Withdrawal/Term Criteria	P11.01: Anytime withdrawal criteria are met but subject was not withdrawn
	2020-12-17 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162186	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-22 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-12 (172)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162195	2020-12-31 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162203	2021-01-12 (138)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3162208	2020-09-08 (9)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3162211	2020-09-08 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162213	2021-02-12 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3162235	2020-12-17 (94)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3162238	2021-02-22 (161)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162240	2020-10-16 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3162243	2020-10-14 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3162255	2021-02-22 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (181)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162262	2020-12-18 (75)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (171)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162263	2020-09-08 (-27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3162269	2020-11-30 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-24 (167)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162270	2020-10-09 (1)	Data Privacy	I01.01: Breach of subject confidentiality
US3162271	2020-12-04 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162273	2020-09-08 (-31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-11 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162274	2021-01-13 (94)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162283	2020-12-10 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-23 (160)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3162301	2020-12-28 (68)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3162304	2020-12-23 (62)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172002	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-11 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172006	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172010	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172010	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3172015	2020-09-04 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3172022	2020-09-29 (51)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-29 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-05 (88)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172025	2021-03-05 (208)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172026	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172027	2020-09-08 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172037	2020-09-15 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172042	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3172043	2020-12-29 (141)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3172047	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172054	2020-08-11	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3172058	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172058	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172066	2020-09-17 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172068	2020-08-11	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3172070	2020-09-18 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-07 (57)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172071	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172075	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172078	2021-02-22 (195)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172095	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172105	2020-11-05 (84)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3172108	2020-09-09 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172113	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172117	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172119	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172126	2021-03-15 (214)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3172131	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3172148	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172152	2020-09-15 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172156	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172166	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-28 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172177	2020-09-16 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-28 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172178	2020-09-22 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172181	2020-10-28 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172184	2020-09-18 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172189	2020-09-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172192	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172193	2021-01-21 (157)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3172194	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172196	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172197	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172199	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-11 (205)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172205	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172211	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-26 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172213	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172215	2020-09-23 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172218	2020-09-23 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172222	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172231	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172232	2020-10-26 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172234	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-21 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172234	2021-01-22 (156)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-28 (162)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3172237	2020-10-27 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172240	2021-02-25 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172250	2020-10-27 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172251	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172252	2020-10-27 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172253	2021-03-01 (194)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172253	2021-03-01 (194)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172256	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172260	2021-03-15 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172266	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172272	2020-10-28 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172277	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172279	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172293	2020-09-28 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172295	2020-10-28 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172299	2020-09-23 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-27 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172303	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172304	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172305	2020-10-29 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172308	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172311	2020-09-24 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172316	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172319	2020-09-24 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172320	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172325	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172329	2020-10-29 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172335	2020-10-02 (39)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172346	2020-09-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172349	2020-09-23 (29)	Inv Safety Rptg (Reg/Sponsor) Study Treatment Admin/Dispense	I12.02: Pregnancy not reported within 24 hours of site awareness P05.09: Participant received less than 2 doses of IP during the study participation
US3172350	2020-10-20 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-27 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172354	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172363	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172369	2020-09-22 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172372	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172381	2020-11-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172400	2020-10-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172403	2020-10-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172405	2020-11-23 (36)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-12-21 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172410	2020-10-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-16 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172412	2020-11-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172422	2020-10-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172425	2020-10-20 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-20 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172427	2020-10-20 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172433	2020-11-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-16 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172434	2020-10-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172435	2020-10-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3172444	2020-11-25 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172444	2020-11-25 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172449	2020-10-20	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3172456	2020-10-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-17 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172460	2020-10-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-25 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3172462	2021-01-04 (76)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-27 (99)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-21 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172462	2021-02-23 (126)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-25 (128)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3172463	2020-10-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172465	2020-10-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-20 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172468	2020-11-18 (29)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
	2020-11-25 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172475	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172475	2020-11-18 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172486	2020-11-27 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3172493	2020-11-27 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3172494	2020-11-19 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172497	2020-11-17 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172498	2020-11-27 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182003	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182004	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182006	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-08 (166)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3182007	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182010	2020-07-27 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182011	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182012	2020-07-27 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-10 (137)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3182013	2020-07-27 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182016	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182017	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182021	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-21 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182026	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-07-31 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3182029	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182030	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-01 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182030	2020-09-08 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182032	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182034	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-02 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182036	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182043	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182044	2020-07-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182044	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182045	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182050	2020-09-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
			P07.10: Subject Diary not completed 30 min post dosing
	2020-12-14 (139)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-08 (164)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-02-17 (204)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3182051	2020-07-29 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182051	2020-08-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182054	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182055	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182060	2020-08-25 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-18 (233)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3182061	2020-08-11 (14)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182065	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182065	2020-07-30 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3182075	2021-02-10 (196)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3182077	2020-09-02 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3182079	2020-08-27 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182083	2020-08-05 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-27 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182101	2020-08-01 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182110	2020-10-07 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182113	2020-09-04 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182115	2020-09-04 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182128	2020-10-07 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182135	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182145	2021-01-08 (158)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3182188	2020-10-02 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182206	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182210	2020-12-06 (123)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3182216	2020-08-12 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-13 (7)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-03 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-28 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182227	2020-09-17 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182230	2020-09-14 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182230	2021-02-11 (189)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3182238	2020-11-20 (106)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-10 (126)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3182242	2020-12-10 (119)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-08 (148)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3182243	2020-12-31 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3182254	2020-08-11 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-13 (4)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-14 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-03-26 (229)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182259	2021-02-19 (194)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182265	2020-09-15 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post dose 2)
US3182266	2020-09-10 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-13 (96)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182306	2020-09-10 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182309	2021-03-22 (223)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3182318	2020-09-08 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182322	2021-02-18 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192003	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192005	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192008	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192009	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192011	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192014	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192015	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192016	2020-08-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-10-11 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192019	2020-08-29 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-17 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-23 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192025	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192028	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192030	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192031	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192032	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192033	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192034	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192039	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-04 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192041	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192043	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192044	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192047	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192049	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192050	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-12 (70)	ICF Process/Timing Visit Scheduling	I02.03: Informed consent not signed and/or dated by subject I02.04: Informed consent not signed and/or dated by appropriate site staff P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192053	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-01 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-09 (190)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-08 (217)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3192054	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192059	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192060	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192061	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192062	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192064	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192069	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192071	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192072	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192073	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192075	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-12 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192078	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192081	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192084	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192085	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192087	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192088	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192089	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192090	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192091	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192094	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-12-18 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192098	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192100	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192101	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192103	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192106	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192107	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192109	2020-08-07 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192110	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192111	2020-08-07 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192111	2020-12-12 (128)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-14 (130)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-17 (133)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-21 (137)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-22 (138)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-23 (139)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-24 (140)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192115	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-10-09 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192117	2020-08-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192117	2020-08-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-19 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192122	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192126	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192128	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192129	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-03 (149)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192130	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192132	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192134	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192136	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192137	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192138	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192141	2020-08-09 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192141	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192144	2020-08-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192145	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192147	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192150	2020-08-09 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192153	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192153	2020-12-23 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192155	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (26)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-10 (123)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3192156	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192157	2020-09-10 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-28 (172)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-23 (198)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192159	2020-09-07 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192166	2020-10-05 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192169	2021-01-03 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192170	2020-10-10 (62)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192172	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-06 (150)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192187	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192197	2020-08-12 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-08 (119)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192199	2020-08-12 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192202	2020-12-17 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192209	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192213	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192214	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192215	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192216	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192217	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192220	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192221	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192225	2020-08-13 (1) 2020-10-23 (72)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192225	2021-01-20 (161)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192227	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject
US3192228	2020-08-13 (1) 2020-12-23 (133)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192229	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192231	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192234	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192235	2020-08-14 (1) 2020-09-24 (42)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-28 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192237	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192238	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192242	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192244	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192246	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192247	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192249	2020-08-14 (1) 2020-12-19 (128)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192250	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192256	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192257	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192258	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192261	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192263	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192263	2020-12-20 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192266	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192267	2020-08-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.10: Subject Diary not completed 30 min post dosing
US3192268	2020-08-15 (1) 2020-09-12 (29) 2020-12-19 (127)	ICF Process/Timing Concomitant Medication Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192269	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192271	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192272	2020-08-15 (1) 2020-12-18 (126)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192273	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192274	2020-08-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192275	2020-08-15 (1) 2020-09-19 (36) 2021-01-14 (153)	ICF Process/Timing Study Procedures/Assessments Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192276	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192281	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192284	2020-08-15 (1) 2020-09-25 (42) 2020-10-23 (70)	ICF Process/Timing Missing Endpoint Assessments Visit Scheduling Visit Scheduling	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window P10.01: Onsite Visits not performed or out of window
US3192285	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192286	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192286	2020-08-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192290	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192291	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192293	2020-08-16 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192294	2020-08-16 (1) 2020-12-28 (135)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192301	2020-08-16 (-10)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192306	2020-08-16 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192307	2020-08-16 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192308	2020-08-16 (-10) 2020-08-26 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192308	2020-12-15 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192309	2020-08-16 (-9)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192312	2020-08-16 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192313	2020-08-17 (-15)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192314	2020-08-17 (-9)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192316	2020-08-17 (-5) 2021-02-06 (169)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3192317	2020-08-17 (-9)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192318	2020-08-17 (-4) 2020-08-21 (1)	ICF Process/Timing ICF Process/Timing	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject
US3192319	2020-08-17 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192321	2020-08-17 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192321	2021-01-13 (146)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192324	2020-08-17 (-6)	ICF Process/Timing	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject
	2020-09-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192325	2020-08-17 (-6)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192326	2020-08-17 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-08-21 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-15 (179)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3192331	2020-08-18 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-21 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192332	2020-08-18 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192333	2020-08-18 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192333	2020-09-18 (28)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192335	2020-08-18 (-7) 2020-09-22 (29)	ICF Process/Timing Concomitant Medication Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P09.01: Prohibited concomitant medication or vaccine received by subject P07.10: Subject Diary not completed 30 min post dosing
US3192336	2020-08-18 (-4) 2020-09-29 (39)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3192337	2020-08-18 (-6)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192339	2020-08-18 (-5) 2020-09-17 (26)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192340	2020-08-18 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192341	2020-08-18 (-9)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192344	2020-08-18 (-4) 2020-12-18 (119)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192346	2020-08-19 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192347	2020-08-19 (-7) 2020-12-23 (120)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192351	2020-08-19 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192354	2020-08-19 (-5) 2020-08-24 (1) 2020-09-21 (29) 2020-11-20 (89)	ICF Process/Timing Missing Endpoint Assessments Missing Endpoint Assessments Visit Scheduling	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window
US3192361	2020-08-19 (-8) 2021-03-23 (209)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol
US3192364	2020-08-19 (-2)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192364	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-09 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192365	2020-08-20 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192366	2020-08-20 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192371	2020-09-26 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192381	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-17 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192384	2020-11-30 (103)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192389	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192400	2021-01-23 (156)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192407	2020-10-27 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192417	2020-12-31 (132)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-07 (139)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3192421	2020-10-10 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192433	2020-11-05 (75)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192437	2020-08-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192437	2020-10-26 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192441	2021-01-04 (135)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-05 (136)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3192445	2020-08-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-13 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192447	2020-09-21 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192466	2020-12-28 (126)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-05 (134)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192468	2020-09-22 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192473	2020-09-22 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192477	2020-08-25 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192484	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-20 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192487	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-21 (118)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-30 (127)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-02 (130)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192487	2021-01-04 (132)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192492	2020-12-23 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192509	2021-01-04 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192513	2020-09-21 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192514	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192515	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192518	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (23)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192520	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3192524	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192526	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192531	2020-11-17 (83) 2020-12-18 (114)	Inv Safety Rptg (Reg/Sponsor) Study Treatment Admin/Dispense	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192535	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192555	2020-12-18 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192562	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192562	2020-11-04 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192563	2020-12-03 (98)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-04 (99)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-06 (101)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-09 (104)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-10 (105)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-11 (106)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192564	2020-12-08 (103)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-09 (104)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-11 (106)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192564	2020-12-12 (107)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3192569	2020-12-28 (122)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-08 (133)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-10 (166)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3192571	2020-11-02 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192577	2020-10-01 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192591	2020-12-21 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192608	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192609	2020-11-03 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192616	2020-12-29 (120)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192618	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192622	2021-01-04 (126)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-05 (127)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192626	2021-02-02 (155)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-04 (157)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-05 (158)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-08 (161)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192628	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192638	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-21 (111)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-22 (112)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3192639	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192641	2020-09-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192654	2020-12-08 (97)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192656	2021-01-15 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192659	2020-10-01 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192660	2021-01-05 (125)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192664	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-29 (118)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192671	2020-11-06 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192679	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192681	2020-10-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-04 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192684	2021-02-12 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3192693	2020-09-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-09 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (104)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192704	2020-11-13 (70)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-07 (94)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3192710	2020-09-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192723	2020-12-23 (83)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192726	2020-10-03 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-30 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-23 (82)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192729	2020-10-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192730	2020-10-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192733	2020-11-03 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192733	2021-01-27 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192748	2020-10-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192749	2020-10-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192752	2021-01-28 (114)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192754	2020-11-05 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192758	2020-12-04 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-11 (96)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192762	2020-12-01 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192769	2020-10-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192772	2020-10-09 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-01 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192773	2020-10-09	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3192779	2020-11-18 (39)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192782	2020-10-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192783	2020-10-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192787	2020-12-07 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192805	2020-12-04 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192807	2020-12-30 (78)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192815	2020-12-18 (66)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192821	2021-02-02 (111)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192824	2020-10-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-11 (58)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-12 (59)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-17 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-19 (66)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-20 (67)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192824	2020-12-21 (68)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-06 (84)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3192826	2020-12-22 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192834	2020-12-29 (75)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192835	2021-01-03 (80)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192845	2020-10-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-06 (114)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192847	2020-12-28 (72)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192850	2020-11-16 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192852	2020-12-18 (62)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192853	2020-10-18 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192856	2021-01-07 (81)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3192880	2020-11-20 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192886	2020-12-22 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192887	2020-12-06 (47)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-08 (49)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-10 (51)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3192890	2020-10-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192900	2020-10-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192911	2020-10-22 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192920	2020-11-22 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192926	2020-11-30 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-16 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202002	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202006	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (41)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3202010	2020-09-10 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-10 (67)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3202013	2020-09-11 (38)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202017	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202017	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-28 (146)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-30 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-05 (154)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-26 (175)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-09 (189)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3202019	2020-09-10 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-16 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202021	2020-10-30 (87)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202021	2020-12-27 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-03 (183)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3202028	2021-03-03 (210)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202030	2020-08-06 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-08-13 (8)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-11 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202032	2020-09-08 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202033	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-11 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202033	2020-09-11 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202038	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3202039	2020-09-03 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3202043	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-23 (171)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-09 (188)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3202047	2020-11-06 (92)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
	2020-11-07 (93)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-11-14 (100)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202047	2020-11-21 (107)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-18 (134)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202049	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-03 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-03 (119)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3202052	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202056	2020-09-18 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202059	2020-09-03 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202059	2021-01-04 (151)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202063	2020-09-11 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-04 (151)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202064	2021-01-05 (152)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3202066	2020-09-10 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202070	2020-09-14 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202071	2020-09-14 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202076	2020-09-16 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202077	2020-09-21 (45)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202080	2020-09-18 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202081	2020-09-12 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202084	2020-09-17 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202085	2020-09-18 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-30 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-11 (215)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202105	2020-09-11 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3202115	2020-09-15 (37)	Missing Endpoint Assessments Visit Scheduling	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window
US3202116	2020-09-22 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202122	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202123	2020-09-18 (39)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3202124	2020-09-18 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202125	2020-08-11 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202125	2020-09-24 (45)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-04 (147)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-24 (167)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-02-09 (183)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202126	2020-09-10 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202133	2020-09-17 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202137	2020-09-24 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202140	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202143	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202144	2020-09-24 (44)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3202146	2020-09-11 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202148	2020-08-12 (1) 2020-09-16 (36)	Missing Endpoint Assessments Study Treatment Admin/Dispense	P07.10: Subject Diary not completed 30 min post dosing P05.09: Participant received less than 2 doses of IP during the study participation
US3202151	2020-09-18 (38) 2021-02-24 (197)	Visit Scheduling Visit Scheduling	P10.01: Onsite Visits not performed or out of window P10.01: Onsite Visits not performed or out of window
US3202152	2020-08-12 (1) 2020-10-04 (54)	Study Treatment Randomization Study Procedures/Assessments	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum) P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202153	2020-08-21 (10)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-15 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202154	2020-12-25 (136)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-28 (139)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-02-02 (175)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202155	2020-09-23 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202159	2020-09-14 (33)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-07 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202160	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202164	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202167	2020-10-05 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-05 (146)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3202168	2020-09-23 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202169	2020-09-24 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202179	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-24 (42)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202182	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202182	2020-09-22 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202183	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202188	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-14 (154)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-12 (183)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3202190	2020-10-02 (50)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-23 (71)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202196	2020-09-14 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3202199	2020-08-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202205	2020-09-22 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202206	2020-10-20 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202210	2020-11-21 (99)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-07 (115)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3202213	2020-09-22 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202217	2021-03-19 (215)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202219	2020-09-18 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202222	2020-10-05 (50)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202225	2020-09-17 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202226	2020-08-17 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3202228	2020-09-24 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202235	2020-08-18 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202235	2020-09-17 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-18 (32)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3202237	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202241	2020-10-07 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-03 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202243	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202245	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202246	2020-09-10 (24)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202253	2020-11-19 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-04 (170)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3202255	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-30 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202258	2020-09-21 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202259	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (34)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3202267	2020-10-29 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202267	2021-02-22 (187)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3202268	2020-11-27 (100)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-04 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202273	2020-08-20 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3202274	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
			P07.10: Subject Diary not completed 30 min post dosing
	2020-11-19 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202278	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202280	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-29 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202281	2020-08-20 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3202284	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202288	2021-01-04 (137)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202289	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-04 (137)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202292	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-03 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202295	2021-02-26 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3202308	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-28 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202309	2020-10-12 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3202311	2020-11-18 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202314	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-19 (148)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202315	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202316	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202317	2020-09-24 (31)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202319	2020-10-02 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-15 (175)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3202326	2020-11-05 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202327	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202328	2020-09-21 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202328	2020-12-01 (98)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-05 (102)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-18 (146)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202340	2020-08-26	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3202348	2020-09-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202350	2020-08-25 (-2)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-30 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-06 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202350	2020-12-11 (107)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-24 (120)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3202354	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-15 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3202357	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202361	2020-10-16 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202363	2020-11-13 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202364	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202364	2020-10-05 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202372	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202374	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202381	2020-11-16 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202393	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202396	2020-09-03 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3202402	2020-09-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202405	2020-12-08 (91)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-04 (118)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3212004	2020-12-17 (137)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3212006	2021-03-01 (211)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212009	2021-03-02 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212012	2021-03-10 (220)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212014	2021-03-01 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212018	2021-02-25 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212027	2021-03-03 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212030	2020-09-15 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212040	2020-09-11 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-07 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212044	2020-10-04 (61)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-10-15 (72)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-10-16 (73)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-10-19 (76)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-10-27 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-29 (86)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3212048	2021-03-02 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212051	2021-02-24 (204)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212066	2020-10-29 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212075	2021-03-08 (215)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212077	2020-08-19 (14)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-03 (29)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3212088	2021-02-22 (200)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212094	2020-09-11 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3212097	2020-12-23 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212107	2020-09-04 (26)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212108	2020-09-11 (33)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3212112	2020-09-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-31 (83)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-11-02 (85)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3212120	2020-09-01 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3212128	2021-01-14 (157)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3212133	2020-12-19 (131)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-21 (133)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3212140	2020-12-16 (127)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-12 (185)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212151	2020-11-20 (101)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-22 (103)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-04 (205)	Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3212167	2020-10-22 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-05 (146)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212169	2020-12-29 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212170	2020-12-21 (131)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212171	2021-03-10 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212175	2020-09-24 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212180	2021-01-10 (150)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-11 (151)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-21 (161)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212181	2020-10-02 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212188	2020-09-29 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212192	2020-12-18 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212222	2020-10-24 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212230	2020-12-16 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212233	2021-03-05 (200)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212235	2020-10-27 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212241	2021-01-20 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3212251	2021-02-23 (189)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212255	2021-03-03 (197)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212257	2020-12-30 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212261	2021-01-31 (165)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-03-10 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212262	2020-12-31 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212269	2021-03-02 (195)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212289	2020-12-18 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212297	2020-09-30 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-19 (207)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212314	2020-09-27 (33)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3212315	2021-02-03 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3212343	2020-09-02	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3212351	2020-12-07 (96)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3212360	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3212381	2020-09-17 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-26 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3212389	2020-11-19 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212396	2021-01-08 (120)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3212397	2021-01-08 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3212412	2021-01-20 (97)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3222003	2020-10-02 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222006	2021-01-08 (156)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222008	2020-09-07 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222011	2020-12-28 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222014	2020-10-30 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222015	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-12 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-02 (89)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222018	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-07 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-07 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222023	2020-09-07 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-22 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222025	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-05 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222029	2020-09-25 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222031	2020-08-12 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-07 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-02 (88)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222033	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-19 (197)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222037	2020-09-12 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-13 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222042	2020-09-02 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222042	2020-09-02 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-21 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222046	2020-09-07 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222048	2020-10-10 (64)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-18 (103)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222049	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222050	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222052	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-05 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222053	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-10-13 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222056	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-07 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-14 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222057	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-07 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222058	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-02-16 (193)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222059	2020-08-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-14 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222064	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-12 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222065	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222067	2020-08-08 (-2)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222068	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222072	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222073	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-11-19 (102)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3222076	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222078	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222080	2020-08-11 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222082	2020-09-12 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222088	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-02 (84)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222089	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-12 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222093	2020-08-12 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-13 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222098	2020-12-28 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222101	2020-09-13 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222102	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-02 (83)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222104	2020-09-13 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222106	2020-08-12 (1)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222110	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222111	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-11 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222114	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-15 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222116	2020-08-16 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-11 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222121	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222124	2020-10-24 (73)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222125	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222128	2020-10-05 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222129	2020-08-13	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3222138	2020-09-15 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222140	2020-09-07 (25)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3222144	2020-09-11 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3222147	2020-09-14 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222151	2020-09-14 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222158	2020-09-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222163	2020-09-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222166	2021-02-07 (177)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-08 (206)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3222168	2020-09-12 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2021-01-07 (146)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222176	2020-08-14 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222185	2021-01-07 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222189	2020-09-20 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222189	2020-11-02 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222195	2021-01-08 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222197	2020-09-16 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222199	2020-09-17 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222202	2020-09-25 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-01 (196)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222203	2020-09-17 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222206	2020-12-29 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222210	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222214	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222216	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-16 (29)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-10-10 (53)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-02 (76)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222219	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222220	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222224	2020-12-29 (133)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222229	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222230	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222238	2020-09-24 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222239	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222246	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222247	2021-01-21 (150)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222249	2020-11-02 (75)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222250	2020-09-19 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222253	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222259	2020-09-17 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-07 (140)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222270	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222271	2020-11-02 (73)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222276	2020-11-13 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222279	2020-08-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222281	2020-09-26 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222284	2020-11-19 (90)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222285	2020-11-16 (87)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222288	2020-08-23 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (58)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222288	2020-11-23 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222289	2020-08-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222290	2020-08-23 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222292	2020-08-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222294	2020-08-23 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222304	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222305	2020-09-29 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222305	2020-12-28 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222306	2020-09-23 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222309	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222315	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222322	2020-09-25 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222326	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-17 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222332	2020-08-29 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222335	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222338	2020-09-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222340	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-30 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222342	2020-09-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222344	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222347	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-01 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222350	2020-08-26 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222350	2020-09-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222354	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-30 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222358	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222360	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222361	2020-12-16 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222363	2020-12-23 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222366	2020-09-28 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222367	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-29 (95)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3222368	2021-02-17 (175)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3222372	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-28 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222374	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222376	2020-08-31 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222377	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222378	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222381	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-24 (89)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222409	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-20 (51)	Missing Endpoint Assessments Study Treatment Admin/Dispense	P07.10: Subject Diary not completed 30 min post dosing P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3222412	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222419	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222422	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222423	2020-11-09 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222430	2020-11-16 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222434	2020-10-01 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222435	2020-11-02 (63)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222438	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222443	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-04 (125)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222446	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222447	2020-10-08 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222448	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222450	2020-12-20 (110)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3222455	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222460	2020-10-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222464	2020-11-02 (61)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222466	2020-09-24 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-11-03 (62)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222467	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222471	2020-10-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222472	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222473	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-05 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-15 (194)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222475	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-18 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222477	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222483	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222484	2021-03-11 (190)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3222490	2020-10-09 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222491	2020-10-02 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222493	2020-09-04 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-01-20 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222497	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-06 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222502	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222502	2020-10-16 (43)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3222506	2020-09-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222509	2020-09-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222510	2020-09-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-10 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222513	2020-09-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222524	2020-09-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-09 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222527	2020-10-06 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222541	2020-10-07 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222542	2020-09-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222545	2021-01-05 (121)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-21 (137)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3222546	2020-09-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222548	2020-10-14 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222550	2020-12-23 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222554	2020-09-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222559	2020-10-07 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222560	2021-03-22 (197)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222561	2020-10-07 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222564	2020-10-08 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222565	2020-10-08 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222580	2020-10-02 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222582	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222584	2020-09-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-24 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222585	2020-10-03 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222592	2020-10-15 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222593	2020-09-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222594	2020-09-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-19 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3222597	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222599	2020-10-16 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222600	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-14 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222602	2020-10-17 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-16 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222604	2021-01-01 (108)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-02-09 (147)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-03-12 (178)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3222606	2020-10-16 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222607	2020-10-16 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222611	2020-09-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222613	2020-09-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222621	2020-09-19 (-6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222624	2020-11-05 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222628	2020-10-17 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222628	2020-10-17 (26)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3222632	2020-12-21 (89)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222636	2020-10-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222640	2020-09-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222642	2020-09-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3222644	2020-10-29 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-04 (160)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222646	2020-09-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222647	2020-09-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222648	2020-10-29 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222653	2020-11-03 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222654	2020-10-30 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-02 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222655	2020-10-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222657	2020-12-27 (88)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3222659	2020-10-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222659	2020-10-04 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-06 (37)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3222661	2020-11-06 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232003	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232004	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232005	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232010	2020-08-25 (19)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232011	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3232013	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3232014	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232028	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3232034	2020-09-09 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3232037	2020-09-10 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-12 (153)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232037	2021-02-09 (181)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232039	2020-09-11 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232043	2020-08-25 (13)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3232063	2020-09-25 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3232081	2020-10-27 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3232092	2021-03-19 (210)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3232097	2020-11-11 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3232110	2020-08-27 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232123	2020-08-28 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232125	2020-08-29 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232132	2021-01-06 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3232137	2020-09-01 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-20 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3232157	2020-09-09 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232158	2020-10-17 (38)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3232159	2020-10-17 (38)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232159	2020-10-17 (38)	Missing Endpoint Assessments Study Treatment Admin/Dispense	P07.06: Nasopharyngeal swab sample not collected when required per protocol P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3232160	2020-10-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232167	2020-09-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3232169	2020-10-17 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3232171	2020-10-17 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3232173	2020-10-19 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232173	2020-10-23 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232174	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232179	2020-09-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3232180	2020-10-17 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3232182	2020-10-20 (32)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-22 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3242002	2020-11-17 (104)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242003	2021-01-25 (173)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-29 (177)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3242015	2020-10-06 (61)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3242019	2020-12-30 (146)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242026	2020-08-06 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3242036	2020-08-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3242091	2020-12-31 (140)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242108	2020-09-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242153	2020-12-12 (116)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-18 (122)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3242186	2020-09-30 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3242225	2020-12-21 (118)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242246	2020-10-05 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3242251	2020-11-09 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242258	2020-11-09 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-17 (79)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3242271	2021-01-28 (150)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242277	2020-10-08 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3242342	2020-10-18 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-06 (144)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3242384	2021-01-27 (125)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3242394	2020-12-01 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242400	2021-01-27 (120)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242408	2020-10-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3242413	2021-02-03 (121)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242413	2021-02-03 (121)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242420	2020-11-14 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252001	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-07 (158)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3252002	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-04 (214)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252009	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-11 (40)	Study Procedures/Assessments Visit Scheduling	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252012	2020-10-03 (62)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252013	2020-12-29 (149)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252015	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252019	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252020	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-17 (14)	Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days
	2020-08-29 (26)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252020	2020-10-22 (80)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3252027	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252032	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252039	2020-12-23 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252041	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252044	2020-09-10 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252045	2021-03-02 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252056	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252062	2021-03-11 (218)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252067	2021-03-10 (216)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252080	2020-09-02 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252083	2021-03-06 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252086	2021-03-06 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252095	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252106	2020-09-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252107	2020-09-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252114	2021-03-04 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252116	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252119	2020-09-11 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-19 (221)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252125	2020-09-09 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-15 (158)	Inv Safety Reporting (CRF)	P07.10: Subject Diary not completed 30 min post dosing
		Inv Safety Rptg (Reg/Sponsor)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252125	2021-01-15 (158)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3252128	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252131	2021-03-09 (210)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252132	2021-03-01 (202)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252145	2021-03-10 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252147	2020-09-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252155	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-03-13 (213)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252160	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252176	2020-10-13 (61)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-02-25 (196)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252202	2021-01-20 (159)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-26 (165)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3252203	2021-03-09 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252211	2020-10-02 (47)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2020-10-23 (68)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252211	2020-11-05 (81)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days
US3252212	2020-09-30 (45)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2020-11-02 (78)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-05 (81)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days
	2021-02-02 (170)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252213	2020-09-15 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252217	2020-09-12 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252222	2020-09-16 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252229	2020-09-23 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3252234	2020-12-25 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252256	2021-03-06 (200)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252281	2021-03-04 (196)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252282	2020-10-15 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252287	2021-01-04 (137)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252304	2020-09-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-08 (140)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3252312	2020-08-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252315	2020-09-25 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252320	2021-03-12 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252327	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252328	2021-03-20 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252334	2020-09-23 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-05 (103)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3252339	2021-01-22 (151)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252347	2021-03-08 (195)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252374	2021-03-05 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252375	2021-03-05 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252377	2021-03-20 (204)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252384	2021-03-23 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252388	2021-01-14 (139)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-16 (141)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-18 (143)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-20 (145)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-02-01 (157)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3252397	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252400	2021-03-09 (190)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252407	2021-03-05 (186)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252408	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-15 (137)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-24 (146)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-12 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3252428	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252431	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252442	2020-11-03 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252455	2020-11-13 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-21 (134)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3252458	2020-11-09 (61)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252465	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252466	2021-03-13 (184)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252478	2020-10-13 (30)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Study Treatment Admin/Dispense	P05.07: Subsequent vaccine administered while contraindicated for a visit (e.g.: Pre-Vaccination Body Temperature =38.0°C/100.4°F)
	2021-02-18 (158)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252485	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252486	2021-01-11 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252492	2020-11-18 (64)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3252497	2020-10-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-06 (170)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252500	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-04 (168)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252503	2020-09-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-13 (176)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252514	2021-03-05 (166)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252518	2020-11-23 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252523	2020-09-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252534	2020-09-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252539	2020-12-31 (100)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252547	2020-12-30 (98)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-11 (169)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252568	2020-09-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252568	2020-09-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-23 (87)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252570	2020-10-26 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252575	2020-10-30 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252577	2021-01-19 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252583	2020-12-05 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-10 (162)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252585	2020-10-02 (3)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-11-26 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252595	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-03 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252602	2021-01-11 (102)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-21 (112)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3252607	2021-03-05 (155)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252612	2021-03-10 (159)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252630	2021-01-06 (93)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-18 (105)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252632	2021-01-22 (109)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-29 (116)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3252634	2020-12-08 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-26 (82)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252638	2020-10-27 (21)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3252642	2020-12-29 (84)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-02-13 (130)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252653	2021-03-09 (149)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252654	2021-03-08 (148)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252657	2020-11-10 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-10 (91)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252659	2021-03-09 (148)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252660	2020-10-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252662	2020-10-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-10 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252666	2020-11-19 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-09 (88)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252666	2021-01-09 (88)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252672	2020-12-20 (67)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252681	2021-01-29 (106)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252689	2020-11-17 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252702	2020-11-24 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252704	2021-01-08 (78)	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3262001	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262007	2020-09-30 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262011	2020-09-04 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-21 (178)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3262020	2021-01-15 (172)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-01 (189)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3262023	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-29 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262024	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262031	2020-07-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-28 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-18 (174)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3262033	2020-08-31 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262037	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262043	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262047	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262048	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262051	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262053	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262054	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262059	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262060	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3262064	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262067	2020-09-01 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3262075	2020-10-30 (89)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262081	2020-10-09 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262082	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262083	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262087	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262091	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262094	2020-08-05 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-23 (231)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262095	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262096	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262099	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3262101	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-06 (94)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262108	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-07 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262109	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3262111	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-17 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-23 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262114	2020-09-08 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-12 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262118	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-20 (168)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3262120	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262121	2020-08-07 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3262122	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262128	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-10 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262128	2020-09-17 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262130	2020-09-15 (40)	ICF Process/Timing	I02.01: Signed informed consent not available on site
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-10 (126)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262132	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262136	2020-09-04 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3262138	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262142	2020-10-12 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262143	2020-09-11 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262146	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262154	2020-09-11 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262156	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262166	2020-10-01 (52)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3262168	2020-10-20 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262172	2020-10-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262184	2020-08-15 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3262185	2020-09-23 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262185	2020-09-23 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262186	2020-09-21 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262188	2020-09-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262199	2020-09-22 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262202	2020-11-24 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262216	2020-09-17 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-11 (177)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3262224	2020-08-26 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3262227	2020-10-05 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262229	2020-09-25 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262249	2020-10-06 (41)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3262255	2020-11-06 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262257	2020-09-05 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-20 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-25 (56)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262264	2020-10-15 (43)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262268	2020-10-05 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3272002	2020-07-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3272004	2020-07-29 (1)	Missing Endpoint Assessments Study Procedures/Assessments	P07.10: Subject Diary not completed 30 min post dosing P08.01: Subject was not observed for at least 30 minutes after vaccination
US3272005	2020-07-29 (1)	Exclusion Criteria Study Treatment Randomization	P03.01: Exclusion criteria met, but subject randomized P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3272009	2020-12-30 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3272018	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272021	2021-01-20 (175)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3272022	2020-08-28 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-05 (68)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3272025	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-10-16 (78)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3272026	2020-09-08 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (117)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272049	2020-09-14 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272055	2020-10-19 (76)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-28 (146)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3272064	2020-09-09 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-08 (156)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3272069	2021-03-08 (215)	Visit Scheduling	P10: Safety call visits not performed or out of window
US3272070	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272075	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272086	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272086	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272104	2021-01-31 (174)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3272107	2020-09-13 (34)	Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-15 (36)	Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-17 (38)	Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol
US3272114	2020-10-28 (78)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3272142	2020-08-14 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-15 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-30 (78)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3272159	2020-08-15 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272171	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272172	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3272174	2020-11-06 (82)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-19 (95)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3272176	2020-09-21 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272177	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272177	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272188	2020-12-20 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-29 (133)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3272195	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3272196	2020-11-05 (79)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-19 (93)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3272206	2020-10-28 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272225	2021-01-12 (145)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3272228	2020-09-28 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272272	2021-02-12 (175)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3272280	2020-09-23 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272288	2020-08-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3272298	2020-12-30 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3272305	2020-11-28 (98)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3272309	2020-08-23 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-08-28 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272317	2020-11-06 (76)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3272324	2020-09-27 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272336	2020-08-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3272340	2020-09-26 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272348	2020-10-29 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272354	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3272357	2020-11-10 (78)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3272361	2020-10-29 (65)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272361	2021-02-27 (186)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3272366	2020-10-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-03 (98)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-04 (130)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272368	2020-10-03 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272375	2020-12-11 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3282002	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3282004	2020-08-31 (27)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3282005	2020-08-31 (27)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3282015	2020-09-11 (37)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3282036	2020-09-14 (34)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3282065	2021-01-12 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3282071	2020-12-17 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3282119	2020-10-26 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-09 (18)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3292002	2021-02-02 (187)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292002	2021-02-02 (187)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-02-12 (197)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-17 (202)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-19 (204)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-22 (207)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-03-23 (236)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3292005	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3292010	2020-12-30 (149)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292024	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292026	2020-12-17 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292027	2020-12-16 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292038	2020-10-01 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3292053	2021-01-13 (159)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292054	2020-12-23 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292058	2021-01-06 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292063	2020-12-24 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292064	2020-08-28 (21)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3292075	2020-10-30 (84)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292082	2020-08-28 (21)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3292092	2020-08-16 (9)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3292098	2020-08-28 (21)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3292100	2021-01-06 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292109	2021-01-12 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3292110	2020-11-06 (88)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292132	2020-08-28 (18)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject I02.04: Informed consent not signed and/or dated by appropriate site staff
US3292144	2020-11-07 (87)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3292149	2020-09-12 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3292154	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3292159	2020-11-07 (87)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3292170	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3292177	2020-09-23 (40)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292188	2020-09-12 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-05 (175)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-09 (179)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3292192	2020-11-07 (85)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3292212	2020-12-18 (123)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292242	2020-11-12 (85)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3292247	2021-01-04 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292248	2020-12-29 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292268	2021-01-10 (143)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292273	2020-12-17 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292280	2020-11-06 (78)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-13 (115)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-14 (116)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3292287	2020-11-06 (78)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292289	2020-11-23 (91)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-11-26 (94)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292292	2021-02-04 (164)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292293	2021-01-11 (140)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292320	2020-12-09 (107)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-14 (112)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292335	2021-01-02 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292346	2021-01-09 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292358	2020-11-06 (70)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292361	2020-12-23 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292377	2020-09-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292379	2020-09-21 (24)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-29 (154)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3292385	2020-12-12 (89)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-14 (91)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292388	2020-11-16 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3292405	2020-12-23 (93)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292407	2020-11-06 (46)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3292408	2020-09-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3292418	2020-11-06 (44)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292423	2020-11-10 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3292427	2020-11-16 (49)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-14 (139)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-23 (148)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292436	2020-11-06 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292452	2021-02-11 (113)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3302001	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302006	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302007	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302008	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302009	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-02 (31)	Missing Endpoint Assessments	P07.03: Subject diary has 2 or more consecutive days of solicited entries missing within one segment (Post Dose 2)
US3302014	2020-09-01 (29)	Missing Endpoint Assessments	P07.03: Subject diary has 2 or more consecutive days of solicited entries missing within one segment (Post Dose 2)
US3302020	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302022	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302032	2021-01-04 (154)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3302036	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302038	2021-01-12 (161)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302042	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-06 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302043	2021-01-08 (157)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302051	2021-02-15 (195)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3302062	2020-12-21 (138)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-29 (146)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302065	2021-01-11 (159)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302069	2021-02-24 (203)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3302079	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302089	2020-09-30 (55)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302102	2020-12-23 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3302103	2020-10-05 (60)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302108	2021-01-21 (167)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302112	2021-03-17 (222)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3302138	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3302143	2021-01-05 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302152	2020-12-18 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3302160	2021-01-08 (150)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302161	2021-01-03 (145)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-05 (147)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302179	2020-09-04 (23)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3302187	2021-01-05 (146)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302192	2021-01-28 (169)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3302202	2021-01-19 (160)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3302208	2021-01-19 (159)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3302210	2021-01-08 (148)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302221	2020-12-07 (116)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-23 (132)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3302223	2020-08-20 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3302229	2021-01-05 (142)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302236	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-05 (142)	Inv Safety Rptg (Reg/Sponsor) Study Procedures/Assessments	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3302240	2021-01-08 (145)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302242	2021-01-12 (149)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302253	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302274	2020-10-14 (57)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302283	2020-10-23 (66)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302289	2020-09-18 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302305	2021-01-08 (142)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302311	2021-01-19 (152)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3302312	2021-01-19 (152)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3302317	2021-01-12 (145)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302318	2021-01-15 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302323	2021-01-19 (152)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302331	2021-01-19 (152)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3302333	2020-10-12 (50)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-10-18 (56)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-20 (58)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-25 (63)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-01 (70)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3302348	2020-12-22 (121)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302359	2021-01-19 (148)	Study Procedures/Assessments	P08.16: More than 30 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3302362	2021-01-12 (141)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302362	2021-02-16 (176)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3302366	2021-01-12 (141)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302371	2020-08-12 (-13)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302373	2021-01-12 (140)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302376	2020-10-27 (63)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302381	2020-12-23 (120)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3302383	2020-09-25 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-09-28 (34)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-30 (36)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-12 (48)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302383	2020-10-19 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3302384	2020-09-25 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302393	2021-01-12 (139)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302398	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302404	2021-03-15 (201)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3302410	2021-01-12 (139)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302411	2020-10-04 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-11 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302414	2021-01-12 (138)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302421	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-21 (55)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302430	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-08 (134)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-02-09 (166)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3302439	2021-01-08 (134)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-02-09 (166)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3302442	2020-12-23 (118)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302445	2021-01-08 (131)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302446	2020-09-30 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302453	2020-10-13 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3302455	2020-09-24 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302462	2020-10-26 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-23 (57)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3302466	2020-12-16 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302470	2021-01-14 (101)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-16 (103)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3302471	2020-11-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3302483	2020-11-23 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312003	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3312037	2020-08-13 (3)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3312039	2020-08-11 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312039	2020-09-10 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312044	2020-08-12 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3312047	2020-12-10 (121)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3312066	2020-09-09 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312101	2021-01-04 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3312117	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312123	2021-01-05 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312128	2020-09-14 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312159	2020-08-18 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312194	2020-08-19 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312201	2020-09-17 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3312212	2020-09-04 (15)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-25 (97)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3312264	2020-08-24 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312273	2020-09-21 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312337	2020-10-05 (40)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3312378	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312406	2020-08-30 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-27 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312446	2021-03-12 (192)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3312452	2020-09-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312460	2020-10-08 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3312464	2020-10-09 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312482	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312526	2020-10-12 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-20 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3312535	2020-11-10 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3312548	2020-11-10 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3312573	2020-10-06 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3322003	2020-09-25 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-02 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-23 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322006	2020-09-27 (42)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-23 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322013	2020-09-14 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-08 (53)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3322014	2020-10-30 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322031	2020-09-25 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-28 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3322047	2021-01-27 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322052	2021-01-25 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322055	2021-02-21 (186)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322060	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3322061	2020-09-14 (25)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-17 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-15 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322064	2020-10-30 (71)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-28 (130)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3322071	2021-02-10 (174)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322073	2020-12-24 (126)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322081	2020-12-22 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322097	2021-01-12 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322098	2020-12-15 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322107	2021-01-12 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322111	2020-09-23 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3322118	2021-01-18 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322123	2021-02-02 (160)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322135	2021-01-06 (131)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322139	2021-01-12 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322165	2021-01-27 (149)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3322168	2020-09-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3322170	2021-01-20 (142)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322175	2021-01-12 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322182	2021-01-13 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322195	2020-10-30 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322203	2020-10-27 (55)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3322204	2020-12-22 (111)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-06 (126)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322215	2020-10-30 (58)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-28 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322225	2021-03-17 (195)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322226	2021-02-25 (175)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3322228	2021-01-16 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322233	2021-01-25 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322240	2021-02-08 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-18 (192)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322242	2021-01-12 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322251	2021-01-16 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322258	2020-12-24 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322259	2021-01-15 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322260	2021-01-22 (137)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322262	2020-12-18 (102)	Study Treatment Admin/Dispense Withdrawal/Term Criteria	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study P11.01: Anytime withdrawal criteria are met but subject was not withdrawn
US3322269	2021-01-27 (141)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322270	2021-02-01 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322273	2021-02-12 (157)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322275	2021-02-01 (146)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322276	2021-02-08 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322277	2020-10-28 (50)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3322281	2021-02-08 (153)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322287	2020-10-06 (28)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-15 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322294	2021-01-06 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322296	2021-01-10 (123)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-02-03 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322297	2020-11-16 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322299	2020-12-26 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322301	2020-12-10 (92)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-02-03 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322303	2021-01-02 (115)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3322305	2021-01-12 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322307	2020-12-24 (91)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-22 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-02-19 (148)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3322313	2020-10-09 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-27 (47)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322316	2020-12-16 (97)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322318	2020-12-19 (100)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322323	2021-01-19 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322325	2021-02-20 (163)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322327	2021-01-13 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322327	2021-01-13 (124)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322330	2021-01-13 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322331	2020-11-05 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-01 (143)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322333	2021-01-13 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322335	2021-02-05 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322338	2020-12-16 (96)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3322342	2021-01-13 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322345	2020-11-09 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322346	2021-01-26 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322347	2021-01-13 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322354	2021-02-01 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322356	2021-03-26 (192)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322361	2021-01-15 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322362	2021-01-23 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322369	2021-01-19 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322370	2021-01-11 (116)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322372	2021-01-11 (116)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322389	2021-02-02 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322394	2021-01-27 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322400	2020-12-04 (59)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322403	2021-01-19 (111)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322406	2021-01-22 (114)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322412	2020-11-19 (46)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3322414	2021-01-19 (107)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322421	2021-01-25 (109)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322423	2020-10-12	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3322427	2021-02-03 (114)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322430	2021-01-19 (98)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3332019	2021-01-06 (154)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3332024	2020-09-08 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3332030	2020-09-10 (35)	Inv Subject Medical Care	I13.01: Failure by the investigator to perform or arrange for the conduct of supplemental measurements and/or evaluations as medically indicated or as requested by Sponsor or representative to elucidate the nature and/or causality of the AE or SAE as fully as possible.
US3332035	2020-09-11 (33)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3332048	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3332052	2020-10-01 (49)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3332066	2020-09-21 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3332068	2021-01-20 (146)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3332071	2020-09-24 (28)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3332077	2020-10-08 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3332087	2020-11-17 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3332094	2020-10-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-04 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3332097	2020-10-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-06 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3332101	2021-01-08 (85)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3332103	2020-11-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342002	2020-09-18 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-16 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342004	2020-12-28 (141)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3342007	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3342019	2021-01-22 (165)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342037	2020-09-18 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-16 (158)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3342043	2020-09-11 (31)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3342046	2020-12-01 (111)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-01-04 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342048	2021-02-08 (180)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3342073	2021-03-09 (208)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3342083	2020-12-29 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342087	2020-12-28 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342088	2021-01-22 (159)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342093	2021-03-08 (203)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342097	2021-03-12 (207)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342103	2020-08-18 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3342122	2020-10-12 (55)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3342123	2020-09-06 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342126	2020-08-20 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3342142	2020-11-23 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.02: Pregnancy not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.04: Contraceptive method not used according to protocol (through 3 months following the second dose (Day 29)
	2021-01-12 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342152	2020-12-29 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3342153	2020-10-13 (47)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3342157	2020-12-30 (122)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342162	2020-09-04 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342163	2020-10-13 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342170	2020-10-21 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342175	2020-10-27 (56)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342182	2020-10-15 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342187	2020-10-16 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342192	2020-10-12 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342192	2020-10-12 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342195	2020-10-23 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342196	2020-10-23 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342201	2020-10-14 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342204	2020-10-26 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-09 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342206	2021-03-12 (186)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3342213	2020-12-01 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342218	2020-12-30 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342223	2020-09-14 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342233	2021-02-03 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3342236	2020-10-16 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342240	2020-10-19 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342240	2020-10-19 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-02 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342259	2020-09-18 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (33)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3342262	2020-11-02 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-30 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342263	2020-10-15 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342273	2020-12-11 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342275	2020-11-03 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342285	2021-01-05 (102)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342290	2020-10-03 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-23 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342295	2021-03-12 (165)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342298	2020-12-01 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342312	2020-11-11 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-12 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3342323	2020-11-14 (31)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-16 (33)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342323	2020-12-01 (48)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-12-02 (49)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-17 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-22 (69)	Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days
US3342334	2020-11-12 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342337	2020-11-19 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-23 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342338	2020-11-14 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342360	2020-10-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342362	2020-11-24 (41)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3352003	2021-01-08 (158)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3352007	2020-09-08 (36) 2021-01-16 (166)	Study Treatment Admin/Dispense ICF Process/Timing	P05.09: Participant received less than 2 doses of IP during the study participation I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352013	2020-08-04 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352031	2020-09-19 (38) 2020-11-02 (82) 2020-12-01 (111)	Visit Scheduling Study Treatment Admin/Dispense Concomitant Medication	P10.01: Onsite Visits not performed or out of window P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352032	2020-08-08 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-11 (218)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352042	2020-11-02 (84)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352049	2020-12-03 (115)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352059	2021-03-11 (213)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3352062	2021-03-23 (223)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352068	2020-12-16 (126)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-22 (222)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352069	2020-12-03 (113)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-21 (221)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352071	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-22 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-13 (123)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3352072	2020-08-27 (15)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-08 (27)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3352074	2020-12-01 (111)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352105	2020-11-02 (77)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352130	2021-02-03 (170)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352139	2020-02-21 (-181)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352153	2020-09-17 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3352156	2021-02-13 (178)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352160	2020-09-23 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352165	2020-08-22 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352173	2020-10-01 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3352174	2020-09-18 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352180	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352181	2020-10-27 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-09 (172)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352182	2021-01-11 (143)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352185	2021-01-11 (143)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352187	2020-12-14 (115)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-12-19 (120)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3352188	2020-12-16 (117)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3352191	2021-01-26 (158)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352191	2021-03-10 (201)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3352192	2021-02-13 (176)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352203	2020-09-19 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-03 (166)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3352204	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352210	2020-09-21 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352211	2021-01-06 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352217	2021-02-03 (166)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352221	2020-09-29 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-02 (73)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352225	2021-02-24 (187)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352235	2020-09-24 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352242	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352245	2020-11-12 (80)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352246	2021-02-18 (178)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352249	2020-09-24 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352251	2020-12-30 (128)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-02-03 (163)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352254	2021-01-19 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352258	2020-11-03 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (107)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-30 (128)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352259	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-17 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-26 (155)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352264	2021-01-26 (155)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352276	2021-01-13 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-02-09 (169)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3352277	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352281	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352281	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-01 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352282	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352292	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-19 (26)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352297	2021-01-20 (142)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3352303	2020-11-03 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (100)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352304	2020-08-25 (-7)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352304	2020-12-29 (120)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3352306	2020-10-03 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352307	2020-12-30 (121)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-05 (127)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3352320	2020-10-09 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352324	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-14 (96)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-18 (162)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352325	2020-10-10 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352330	2021-01-13 (126)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3352337	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3352349	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3352350	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3352351	2020-09-14 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352354	2020-09-11 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352364	2020-09-13 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352368	2020-09-10 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-03 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (91)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352372	2020-11-12 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352379	2021-01-11 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3352388	2020-11-03 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (82)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352408	2020-10-25 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352409	2021-01-05 (104)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3352415	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352418	2020-11-16 (54)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3352422	2020-11-03 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-17 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352430	2020-10-26 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352432	2020-10-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352438	2021-01-11 (105)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352442	2021-02-26 (151)	Study Treatment Randomization	P04.03: Subject enrolled/dosed at two sites
US3352447	2020-11-03 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-12 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352448	2020-10-30 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-17 (111)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-03 (128)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3352450	2020-09-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352456	2020-10-03 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-27 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352457	2020-11-05 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352462	2020-10-01 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352467	2020-11-12 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352468	2020-12-09 (72)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352471	2020-11-12 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-11 (105)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352479	2020-10-27 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-02-13 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352482	2020-11-05 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352487	2020-11-12 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-14 (47)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352493	2020-11-06 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352495	2021-03-25 (171)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352505	2020-10-10 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352508	2020-10-13 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352511	2020-10-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-02 (146)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352516	2020-11-03 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352521	2020-10-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-03 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352530	2020-10-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352541	2020-12-09 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352545	2020-10-16 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-13 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352551	2020-10-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-14 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-22 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352556	2020-11-21 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352557	2020-12-09 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-02-09 (118)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352567	2020-12-09 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352568	2020-10-20 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352581	2020-11-08 (25)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-24 (41)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-02 (49)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3352588	2020-11-22 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352590	2020-11-27 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352591	2020-11-22 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-13 (84)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352597	2020-11-22 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352600	2020-10-24 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-09 (49)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352603	2021-01-26 (97)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3362004	2020-08-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362005	2020-08-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362012	2020-12-16 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3362018	2021-01-08 (159)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362019	2020-09-10 (39)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-20 (171)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3362029	2021-03-05 (214)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-07 (216)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-09 (218)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3362030	2020-09-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362041	2020-10-15 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362046	2020-12-01 (119)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3362053	2020-12-18 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362058	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3362061	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362075	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3362085	2020-09-09 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362094	2020-08-22 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3362096	2020-09-18 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362101	2020-09-25 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362110	2021-01-06 (149)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3362111	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362120	2020-09-18 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362130	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362141	2020-09-25 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362142	2020-09-21 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362147	2020-08-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362162	2020-09-21 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362167	2020-09-15 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362168	2021-01-25 (162)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-01 (169)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3362180	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (39)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362181	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-30 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-09 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362183	2020-10-13 (57)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362184	2020-09-25 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-01 (45)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362186	2020-10-13 (57)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362196	2020-09-25 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3362199	2020-08-29 (10)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-25 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362206	2020-10-13 (55)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362208	2020-08-24 (5)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362228	2020-08-24 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3362248	2020-10-02 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362276	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-11 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362279	2020-10-08 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362281	2020-09-11 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-12-03 (84)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3362290	2020-10-30 (35)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362300	2020-10-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3362305	2020-10-09 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-14 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372005	2020-09-15 (43)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3372008	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372014	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372017	2020-09-03 (32)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372020	2020-08-07 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372021	2020-09-03 (32)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372023	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372028	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (24)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372036	2020-09-12 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372045	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372051	2020-12-31 (147)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3372060	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372086	2021-01-20 (163)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3372103	2020-12-21 (132)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3372107	2020-09-23 (43)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3372115	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3372116	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372124	2021-01-06 (146)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3372126	2020-08-26 (13)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-25 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3372133	2020-09-17 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372138	2021-01-20 (157)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3372139	2020-12-21 (127)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3372144	2021-01-07 (144)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3372149	2020-09-16 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372152	2020-09-17 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372153	2020-08-24 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3372158	2020-09-18 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372189	2021-01-20 (154)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3372198	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372229	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-28 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372229	2021-02-14 (175)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3372234	2021-01-20 (149)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3372242	2020-10-01 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372260	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372269	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3372283	2020-10-02 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372284	2020-12-11 (106)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372290	2020-11-27 (92)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3372316	2020-10-08 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (85)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372322	2020-10-08 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372326	2020-10-22 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372327	2020-10-22 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372329	2020-10-19 (47)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372341	2021-02-23 (173)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3372348	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372361	2020-11-23 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372362	2020-10-19 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3372374	2021-03-17 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3372383	2020-09-16 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3372384	2020-11-25 (73)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372385	2020-10-19 (40)	Missing Endpoint Assessments Study Treatment Admin/Dispense Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3372390	2021-01-20 (133)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372395	2020-11-02 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-16 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372413	2020-09-28 (15)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3372428	2021-01-29 (136)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3372429	2021-02-09 (147)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3372446	2020-10-23 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372451	2020-09-27 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-19 (27)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3372459	2020-10-01 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372473	2021-03-04 (147)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3372480	2020-10-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3382012	2021-02-23 (197)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3382016	2020-09-14 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-31 (82)	Study Treatment Admin/Dispense	P05.07: Subsequent vaccine administered while contraindicated for a visit (e.g.: Pre-Vaccination Body Temperature =38.0°C/100.4°F)
US3382075	2020-09-25 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3382084	2020-08-19	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3382085	2020-08-19 (-1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382085	2020-09-25 (37)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Visit Scheduling	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
			P10.01: Onsite Visits not performed or out of window
US3382096	2021-01-04 (134)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3382097	2020-12-04 (103)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-11 (110)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3382108	2020-09-02 (9)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-15 (22)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3382127	2020-09-26 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382131	2020-12-22 (118)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382133	2020-12-20 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382159	2021-01-02 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382162	2020-10-13 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3382180	2020-10-10 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Procedures/Assessments	P08.07: Subject was not instructed/reminded to report solicited ARs in eDiary after each dosing visit (Day 1 and Day 29)
US3382215	2020-09-08 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3382217	2020-09-08 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-25 (199)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382218	2020-09-08 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3382221	2020-10-08 (31)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3382226	2020-10-07 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382229	2020-10-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382237	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3382242	2020-10-11 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382244	2020-09-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382246	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3382280	2020-10-17 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382281	2021-01-19 (127)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-03-15 (182)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3382287	2021-02-16 (153)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3382289	2020-09-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3382295	2020-10-20 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-26 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3392001	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392001	2020-12-03 (115)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3392006	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392007	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392008	2020-08-11 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392010	2020-12-07 (117)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-14 (124)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392013	2020-08-12 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392017	2020-09-08 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392019	2020-09-08 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392024	2020-08-13 (-4)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392038	2020-09-14 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392040	2020-08-17 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392044	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392045	2020-09-14 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392053	2020-09-21 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392068	2020-12-22 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392075	2020-09-23 (31)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392080	2020-09-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392084	2020-09-22 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392089	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392094	2020-09-23 (28)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392104	2020-09-03 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392110	2020-09-22 (26)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392111	2020-09-22 (26)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-04 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392115	2020-09-22 (26)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392116	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-22 (26)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392122	2020-08-30 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392125	2021-02-11 (165)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3392135	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392138	2020-12-01 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3392140	2021-01-20 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392142	2020-09-29 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392146	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392157	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392159	2020-08-25 (-9)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392163	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-30 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392166	2020-09-03 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-30 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392168	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392171	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-30 (27)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392179	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392182	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-10 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3392184	2021-01-04 (118)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3392193	2020-10-07 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3392194	2020-10-07 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392195	2020-12-21 (104)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392231	2020-11-04 (55)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3392235	2020-10-16 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-17 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3392237	2020-10-07 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392238	2020-10-07 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392251	2020-11-12 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3392253	2020-09-11 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392254	2021-01-28 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392260	2020-09-11 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-12 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392275	2020-10-09 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392277	2020-12-21 (99)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392279	2021-01-06 (115)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3392280	2021-02-04 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392301	2020-10-14 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392302	2020-09-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392302	2020-10-13 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392305	2020-10-13 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3392309	2020-12-17 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3392330	2020-12-22 (96)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392332	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392341	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392341	2021-03-04 (165)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3392344	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-17 (146)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3392352	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392354	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3402001	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402002	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402002	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402004	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402008	2020-07-26 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402013	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402016	2020-07-26 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-27 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-08-27 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-29 (187)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402026	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402029	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402030	2020-12-28 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3402040	2020-07-28 (1)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3402057	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-30 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402065	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402072	2020-07-29 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402074	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402076	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402077	2020-08-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402089	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402091	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402104	2021-01-27 (182)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3402114	2020-11-10 (104)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3402117	2020-09-11 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402118	2020-09-08 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3402121	2020-10-01 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3402134	2020-07-31 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402137	2020-12-29 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3402138	2020-07-31 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402142	2020-07-31 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402143	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402175	2021-02-01 (184)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402176	2020-08-02 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-07 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402183	2020-09-02 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-07 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402190	2020-08-01 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402192	2020-09-04 (34)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-09 (69)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3402194	2020-11-13 (104)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3402202	2020-10-21 (80)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402206	2020-09-01 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402209	2020-09-11 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402214	2020-08-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3402221	2020-09-09 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402235	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402236	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402245	2020-09-02 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3402252	2020-09-03 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402261	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-03 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-18 (105)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402262	2020-09-03 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402264	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402281	2020-09-26 (51)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402294	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402295	2020-09-22 (46)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402301	2020-08-08 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3402314	2020-09-15 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402325	2020-09-14 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402328	2021-01-22 (165)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3402332	2020-12-03 (114)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3402340	2020-10-26 (74)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402348	2020-08-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402356	2020-09-21 (38)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402358	2020-11-27 (105)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3402364	2020-09-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402382	2020-09-14 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3402390	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402394	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402397	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402401	2020-08-22 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402405	2020-09-15 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Procedures/Assessments	P07.10: Subject Diary not completed 30 min post dosing P08.01: Subject was not observed for at least 30 minutes after vaccination
US3402408	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-26 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402415	2020-11-22 (93)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3402430	2020-09-21 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402440	2020-08-22 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3402441	2020-09-06 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402453	2020-10-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402456	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412001	2020-09-16 (51)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412003	2020-08-21 (25)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412004	2020-09-16 (51)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412005	2020-08-21 (25)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-24 (240)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3412008	2020-08-21 (24) 2021-01-05 (161)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3412010	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412011	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412012	2020-10-22 (86)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412018	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412020	2020-08-21 (24)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412022	2020-09-16 (50) 2020-11-12 (107)	ICF Process/Timing Inv Safety Rptg (Reg/Sponsor)	I02.02: Wrong informed consent version signed I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412024	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412025	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412026	2020-08-21 (24)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412027	2020-07-29 (1) 2021-01-05 (161)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3412030	2020-09-16 (49) 2021-01-05 (160)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3412031	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412033	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412036	2020-07-30 (1) 2020-08-26 (28)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.10: Subject Diary not completed 30 min post dosing
US3412040	2020-09-01 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412044	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412047	2020-08-21 (23) 2020-08-22 (24)	ICF Process/Timing Concomitant Medication	I02.02: Wrong informed consent version signed P09.01: Prohibited concomitant medication or vaccine received by subject
US3412048	2020-08-21 (23) 2020-10-06 (69) 2021-02-25 (211) 2021-02-27 (213) 2021-03-09 (223)	ICF Process/Timing Visit Scheduling Visit Scheduling Concomitant Medication Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window P10.01: Onsite Visits not performed or out of window P09.01: Prohibited concomitant medication or vaccine received by subject P10.01: Onsite Visits not performed or out of window
US3412049	2020-08-21 (23) 2020-09-24 (57)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3412050	2020-07-30 (1)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412051	2020-07-30 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412055	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412055	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412060	2020-10-06 (68)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412061	2020-07-31 (1) 2021-03-13 (226)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3412063	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412064	2020-07-31 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3412066	2020-07-31 (1) 2020-08-28 (29) 2021-03-16 (229)	ICF Process/Timing Missing Endpoint Assessments Visit Scheduling	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412068	2020-08-21 (22)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412073	2020-12-03 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412074	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412075	2020-07-31 (1) 2020-08-06 (7)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3412076	2020-10-13 (75)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412078	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412080	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412081	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412082	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412084	2020-08-21 (22)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412086	2020-10-13 (75) 2020-10-21 (83)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412086	2021-02-22 (207)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3412087	2020-08-28 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-13 (75)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412089	2020-07-31 (-11)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412092	2020-08-01 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412093	2020-08-01	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412095	2020-08-01 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412097	2020-08-01 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412098	2020-08-01 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412099	2020-08-01 (-26)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-10-05 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3412103	2020-12-03 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412104	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-04 (94)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412105	2020-08-21 (19)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412106	2020-12-03 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412107	2020-12-03 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412108	2020-08-21 (19)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412111	2020-08-21 (19)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412118	2020-08-21 (18)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412120	2020-08-04 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412122	2020-08-21 (18) 2020-09-08 (36)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3412123	2020-08-04 (1) 2021-01-05 (155)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.18: Less than 20 minutes for completion of mRNA-1273 vial equilibration to room temperature 20°C to 25°C
US3412130	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412132	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412133	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412133	2020-09-17 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3412134	2020-08-21 (17)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412137	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412139	2020-12-29 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412141	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-03 (152)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-25 (174)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3412146	2020-08-21 (17)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-12 (161)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3412148	2020-08-21 (17)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-15 (223)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-24 (232)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3412149	2020-08-21 (16)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412152	2020-10-13 (69)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412155	2020-08-06 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-08-21 (16)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412156	2020-08-06 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412158	2020-08-07 (2)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412160	2020-08-09 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-16 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3412162	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412166	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412168	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412170	2020-08-07 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412171	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412173	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412175	2020-12-30 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412177	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412178	2020-09-16 (38)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412179	2020-08-10 (1) 2021-03-15 (218)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3412180	2020-08-07 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412183	2020-08-10 (1) 2020-12-28 (141)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3412184	2020-10-07 (59)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412185	2020-08-10 (1) 2020-09-13 (35) 2020-09-15 (37)	ICF Process/Timing Missing Endpoint Assessments Visit Scheduling	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P10.01: Onsite Visits not performed or out of window
US3412190	2020-08-10 (1) 2020-09-03 (25)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412191	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412192	2020-09-14 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-16 (38)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-10-19 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-23 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3412197	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412198	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412202	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412205	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412208	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-12-31 (143)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-07 (150)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-19 (162)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412208	2021-01-27 (170)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3412210	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412211	2020-08-12 (1) 2020-10-12 (62)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol
US3412212	2020-08-12 (1) 2020-09-14 (34)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412214	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412219	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412224	2020-12-28 (137)	Missing Endpoint Assessments Visit Scheduling	P07.07: Saliva sample not collected when required per protocol P10.01: Onsite Visits not performed or out of window
US3412245	2020-08-19 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412245	2020-09-14 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412247	2020-12-28 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3412259	2020-11-09 (85)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3412278	2020-09-02 (15)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-30 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3412284	2020-12-30 (133)	Inv Oversight	I05.01: Lack of PI oversight
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-17 (182)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3412291	2021-03-04 (197)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412297	2021-02-24 (189)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-15 (208)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3412298	2020-09-15 (26)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3412300	2020-11-10 (79)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3412304	2020-11-05 (74)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3412306	2020-10-20 (58)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3412314	2020-09-21 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-31 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-13 (142)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3412326	2020-10-20 (49)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412328	2020-10-05 (41)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-06 (42)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3412332	2020-09-18 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3412342	2020-10-05 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412356	2020-10-05 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412357	2020-09-04 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412359	2020-09-03 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-16 (14)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412361	2020-10-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-20 (48)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412364	2020-09-03 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3412369	2020-12-18 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-05 (125)	Inv Randomization/Unblinding	I07.01: Unblinding of subject by sponsor/CRO personnel not done per study procedures
US3412372	2020-10-12 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3422003	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3422016	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422021	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422039	2020-09-09 (23)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422060	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422062	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3422063	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-22 (3)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3422068	2021-01-08 (142)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3422070	2020-10-27 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422087	2021-01-04 (134)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422087	2021-01-06 (136)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3422089	2020-10-06 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422118	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422126	2020-11-10 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422144	2021-01-11 (137)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3422145	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3422168	2020-10-07 (37)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3422171	2020-09-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422201	2021-01-03 (123)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3422208	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422220	2020-09-08 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-10-16 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-29 (52)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3422232	2020-10-06 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422248	2020-10-07 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3422271	2020-09-11 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422276	2020-11-16 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-11 (89)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3422281	2020-11-24 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422288	2020-11-18 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422293	2020-10-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422309	2020-10-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432006	2020-09-14 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-19 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432015	2020-08-10 (6)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432020	2020-12-18 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432023	2020-08-07 (3)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3432029	2020-09-15 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3432038	2020-12-26 (143)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432046	2020-08-13 (7)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-11 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432058	2020-12-18 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432068	2020-08-18 (9)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-09-22 (44)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432082	2020-12-29 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432090	2020-10-14 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-10 (184)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3432097	2020-09-09 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432098	2020-08-11 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3432113	2020-09-15 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432121	2021-01-02 (143)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3432137	2020-12-24 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432149	2021-01-07 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432153	2021-01-12 (152)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-08 (179)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3432169	2020-12-14 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432171	2020-12-18 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432183	2020-11-20 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432202	2020-11-02 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432211	2021-01-04 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432215	2020-11-09 (82)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432228	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432232	2020-10-15 (37)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432246	2021-02-25 (188)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3432248	2020-08-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432249	2020-10-02 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432252	2020-12-21 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432255	2021-02-20 (162)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432256	2020-12-18 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432271	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432285	2020-12-22 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432289	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-22 (90)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-21 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432291	2020-08-30 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3432295	2020-10-02 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432307	2020-08-27 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432309	2020-11-28 (95)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432328	2021-01-21 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432335	2020-11-05 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432345	2020-09-28 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432367	2020-11-03 (65)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432373	2021-02-15 (169)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3432376	2020-10-01 (32)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432380	2021-01-16 (138)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-16 (197)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432383	2020-10-21 (51)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-28 (150)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3432385	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432386	2020-09-25 (25)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432387	2020-11-04 (65)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-17 (78)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-18 (109)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432394	2020-10-05 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432396	2021-01-11 (132)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3432404	2020-10-04 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432404	2021-03-01 (181)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432415	2020-10-02 (30)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3432416	2021-01-21 (141)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432424	2021-01-19 (138)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3432431	2021-01-27 (146)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432435	2020-10-19 (46)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-03-13 (191)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432439	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3432453	2020-12-22 (109)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432466	2020-10-02 (25)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3432467	2020-11-03 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-30 (145)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-27 (173)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3432473	2020-09-25 (17)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-14 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432489	2020-12-04 (85)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-08 (89)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-20 (132)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-30 (142)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432505	2020-12-21 (97)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432521	2020-12-28 (103)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-05 (111)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432524	2020-10-30 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432527	2020-10-30 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432530	2020-10-27 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (91)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432537	2020-12-21 (92)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432542	2020-11-03 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432562	2020-10-31 (37)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-18 (85)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432564	2020-11-18 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432579	2020-10-30 (30)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3432585	2020-12-19 (79)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432591	2020-11-30 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432592	2020-12-28 (83)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432598	2020-11-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432599	2020-10-09 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3432602	2021-01-08 (88)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432603	2020-12-21 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432610	2020-11-22 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-15 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432613	2020-12-24 (70)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432617	2020-10-19 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432617	2020-12-02 (44)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432636	2021-02-03 (105)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432637	2020-12-19 (59)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432643	2020-12-30 (70)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432645	2020-12-22 (62)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-09 (80)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432649	2020-11-09 (18)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3442004	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442005	2020-08-12 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3442007	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442008	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442009	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3442011	2020-08-12 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-21 (70)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442012	2020-10-02 (51)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-11 (152)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3442014	2020-09-08 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3442017	2021-01-03 (143)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3442029	2020-10-02 (46)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3442039	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442049	2020-12-28 (131)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3442051	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-17 (151)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442052	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442057	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-05 (46)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3442063	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-25 (217)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3442065	2020-11-18 (90)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3442067	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442069	2020-11-12 (84)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-14 (116)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3442071	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442074	2021-03-08 (196)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-22 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3442075	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442084	2020-09-23 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-06 (135)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3442089	2020-08-24 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442092	2020-08-25 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442096	2020-12-28 (124)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3442099	2021-01-04 (131)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3442102	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-21 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3442103	2020-08-27 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3442104	2020-12-31 (126)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3442107	2020-08-27 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442107	2020-09-26 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-11 (137)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-19 (145)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3442110	2020-08-28 (-4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3442131	2020-12-28 (116)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3442133	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442137	2020-08-28 (-17)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-21 (38)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442144	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442152	2020-10-21 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3442161	2020-10-22 (38)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3442163	2020-10-21 (37)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3442171	2020-09-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442172	2020-10-15 (30)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3442173	2020-12-12 (88)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3442174	2020-10-15 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442176	2020-10-21 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3442192	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442195	2020-09-13 (-5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442205	2020-10-29 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442213	2020-10-30 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442214	2020-10-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442221	2020-12-10 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442234	2020-11-18 (36)	Missing Endpoint Assessments Study Treatment Admin/Dispense Visit Scheduling	P07.01: Blood sample not taken when required per protocol P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3442235	2020-10-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-25 (135)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3442240	2020-11-11 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3442246	2020-10-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-16 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452001	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452003	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452004	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452007	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452011	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452012	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452018	2020-08-27 (29)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3452020	2020-08-26 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452023	2020-07-29 (-1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-08-27 (29)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3452030	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452041	2020-12-14 (138)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452081	2020-08-06 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452083	2021-01-07 (160)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452084	2020-09-08 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3452099	2021-03-16 (228)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3452102	2021-01-13 (166)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3452107	2021-02-11 (195)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3452115	2021-01-21 (174)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452119	2020-08-02 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452136	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3452137	2020-12-02 (122)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3452139	2020-08-07 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-25 (207)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452140	2020-08-30 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-25 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452166	2021-03-18 (227)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3452168	2020-09-02 (30)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2020-12-03 (122)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-21 (171)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3452176	2021-02-03 (184)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-02-08 (189)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3452204	2020-08-07 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452204	2020-09-03 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452212	2021-01-21 (171)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3452235	2020-09-05 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452244	2020-12-07 (125)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452253	2020-08-08 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452255	2020-08-07 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452263	2021-01-05 (153)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452278	2020-12-05 (122)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3452282	2020-08-13 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-05 (153)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452293	2020-08-08 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452295	2020-08-18 (13)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3452306	2020-09-10 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452313	2020-12-23 (139)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452324	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-09 (187)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3452331	2020-10-26 (81)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-11-05 (91)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3452332	2020-11-05 (91)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-12-03 (119)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-02-08 (186)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3452337	2020-09-22 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452339	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452355	2020-09-03 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (38)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3452360	2020-09-12 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-14 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452369	2021-02-11 (149)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3452373	2021-01-11 (112)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452373	2021-01-11 (112)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452379	2020-09-21 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452382	2020-09-23 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452388	2020-10-21 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452389	2020-10-23 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452393	2020-10-27 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452400	2020-09-25 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452403	2020-09-26 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-22 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3452405	2020-09-28 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452406	2020-12-16 (83)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452407	2020-09-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3452408	2020-11-02 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452415	2020-10-30 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452416	2020-11-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452425	2021-03-12 (145)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462027	2021-01-12 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-10 (191)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-11 (192)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3462028	2020-10-13 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462032	2020-08-04 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-09 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462042	2020-08-04 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462043	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462049	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-22 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462050	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462051	2020-11-21 (108)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3462060	2021-01-12 (160)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462077	2020-10-02 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462088	2020-09-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-12 (215)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3462090	2021-01-12 (156)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3462106	2020-09-18 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462111	2020-09-15 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462114	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462116	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3462130	2020-10-08 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462140	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462142	2020-09-09 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3462147	2021-02-11 (184)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3462151	2020-09-17 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462152	2020-09-17 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462161	2020-12-27 (137)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462161	2021-01-07 (148)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-03 (175)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3462196	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-21 (39)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-02 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-12 (60)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462197	2020-09-25 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-09 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462205	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462207	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-22 (159)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462229	2020-09-22 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462250	2020-09-15 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462251	2021-01-09 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3462252	2021-01-09 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3462269	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462276	2021-01-12 (146)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3462283	2020-09-30 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462299	2020-11-16 (85)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462299	2020-11-20 (89)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-11-21 (90)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3462308	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462309	2020-09-22 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462315	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-12 (201)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3462323	2021-02-10 (170)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3462348	2020-09-21 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462363	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3462375	2021-01-13 (140)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3462378	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-15 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462388	2020-10-12 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-03-12 (194)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462389	2020-10-12 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-03-03 (185)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3462396	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-30 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462398	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462400	2021-02-26 (179)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-05 (186)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3462405	2020-10-01 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462421	2021-01-13 (127)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3472003	2020-09-16 (17)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-21 (22)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3472005	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3472018	2021-01-22 (141)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-19 (197)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472022	2020-11-02 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472041	2021-02-22 (162)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472044	2021-02-10 (149)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3472061	2020-10-19 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3472063	2021-01-14 (116)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-11 (144)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3472071	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3472081	2020-09-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-08 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3472090	2020-10-30 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3472092	2020-11-02 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3472096	2020-11-30 (55)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3472099	2020-12-28 (82)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-03 (88)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-06 (91)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3472099	2021-01-10 (95)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3472104	2020-12-07 (60)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472105	2021-03-19 (162)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472112	2021-03-18 (154)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3472118	2020-11-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482001	2020-09-17 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3482005	2021-01-17 (161)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3482016	2021-01-05 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482026	2020-09-21 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3482027	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-18 (191)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3482036	2020-12-29 (139)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3482038	2020-08-13 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-10 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482045	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-14 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482046	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3482052	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3482054	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3482081	2020-12-19 (123)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3482083	2020-12-17 (121)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482101	2020-08-20 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3482105	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482110	2020-10-09 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482111	2020-12-19 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3482115	2020-08-24	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
	2020-10-15	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3482116	2020-08-27 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3482135	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3482145	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-15 (51)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3482211	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482235	2020-12-21 (109)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3482246	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482253	2020-09-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3482262	2020-10-16 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3482277	2020-11-24 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3482281	2020-11-05 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482286	2021-01-12 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3482298	2021-01-04 (81)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482302	2021-01-28 (102)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-03 (108)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-17 (150)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3482315	2020-10-21	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-11-20	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3482320	2020-12-31 (71)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-04 (75)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3492001	2021-01-11 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492004	2021-01-13 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492005	2021-01-11 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492007	2020-10-20 (57)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-19 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492017	2020-08-27 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-12 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492018	2021-01-14 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492019	2021-01-12 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492020	2021-01-11 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-11 (196)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3492026	2020-09-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-11 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492027	2021-01-11 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492028	2021-01-12 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492030	2021-01-13 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492031	2021-01-12 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492033	2020-08-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3492035	2021-01-20 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492042	2021-01-14 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492043	2020-12-21 (112)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3492045	2021-01-15 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492046	2021-01-13 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492048	2021-01-15 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492049	2021-01-15 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492050	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3492052	2021-01-08 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492054	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492059	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3492060	2021-01-13 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492064	2021-01-14 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492065	2021-01-11 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492067	2020-12-21 (109)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-15 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492068	2021-01-19 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492071	2021-01-15 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492075	2020-09-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-09 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-19 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492081	2021-01-12 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492082	2021-01-19 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492086	2021-01-21 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492088	2021-01-14 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492089	2020-11-12 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-21 (105)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-29 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492090	2021-01-12 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492091	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3492097	2021-01-11 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492099	2021-01-20 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492101	2021-01-11 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492104	2020-11-13 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492110	2020-09-09 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3492111	2020-12-19 (101)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3492115	2020-09-10 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-29 (142)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-07 (151)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-19 (191)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3492117	2020-10-08 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3492120	2021-01-14 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492120	2021-03-12 (184)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3492130	2021-01-12 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492140	2020-10-13 (32)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-12 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492142	2020-10-20 (39)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3492144	2021-01-20 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492146	2021-01-20 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492156	2021-01-19 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492158	2021-01-12 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-18 (157)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3492162	2021-01-13 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492176	2021-01-12 (119)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492177	2021-01-19 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492178	2021-01-15 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492181	2020-10-14 (28)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3492190	2020-10-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2021-01-14 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492194	2020-12-22 (96)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3492198	2021-01-12 (117)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492199	2021-01-11 (116)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492200	2020-12-21 (95)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-16 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492201	2021-01-15 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492205	2021-01-21 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492209	2020-10-20 (32)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-19 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492211	2021-01-14 (118)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492218	2021-01-21 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492219	2021-01-13 (115)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492220	2021-01-14 (116)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492224	2021-01-08 (110)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492230	2020-10-21 (30)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-20 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492233	2020-10-20 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492233	2020-10-20 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492234	2020-10-20 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492236	2020-10-20 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-21 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492238	2020-10-20 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492239	2020-10-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3492240	2021-01-19 (119)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492242	2021-02-02 (133)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3492248	2021-01-12 (112)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492251	2021-01-08 (107)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492257	2021-01-20 (118)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492263	2021-01-08 (106)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492268	2021-01-11 (105)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492274	2021-01-20 (113)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492277	2020-12-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-20 (113)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492278	2021-01-20 (113)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-03-11 (163)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3492280	2020-11-02 (34)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-15 (108)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492281	2021-01-13 (105)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-15 (107)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492282	2020-11-02 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-13 (105)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492283	2021-01-12 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492285	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-13 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492289	2021-01-12 (100)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492293	2021-01-12 (97)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492295	2021-01-15 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492296	2021-01-12 (93)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492298	2021-01-12 (92)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492302	2021-01-13 (92)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492303	2021-01-14 (93)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492304	2021-01-20 (98)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492307	2021-01-13 (87)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3502004	2020-12-03 (106)	Data Privacy	I01.01: Breach of subject confidentiality
US3502007	2020-12-03 (105)	Data Privacy	I01.01: Breach of subject confidentiality
US3502008	2020-12-03 (105)	Data Privacy	I01.01: Breach of subject confidentiality
US3502016	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-25 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502017	2020-12-03 (102)	Data Privacy	I01.01: Breach of subject confidentiality
US3502018	2020-12-03 (102)	Data Privacy	I01.01: Breach of subject confidentiality
US3502022	2020-09-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3502024	2020-12-03 (101)	Data Privacy	I01.01: Breach of subject confidentiality
US3502031	2020-12-03 (100)	Data Privacy	I01.01: Breach of subject confidentiality

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502035	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3502038	2020-12-03 (99)	Data Privacy	I01.01: Breach of subject confidentiality
US3502042	2020-12-03 (99)	Data Privacy	I01.01: Breach of subject confidentiality
US3502043	2020-12-03 (99)	Data Privacy	I01.01: Breach of subject confidentiality
US3502057	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502085	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-11 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3502097	2020-09-21 (18)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3502113	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502121	2021-03-04 (178)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3502132	2020-10-13 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3502134	2020-09-21 (12)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3502139	2020-10-14 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3502147	2020-10-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3502149	2020-09-21 (11)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502152	2020-10-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3502154	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502160	2020-09-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502167	2020-12-03 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3502173	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-03 (73)	Data Privacy	I01.01: Breach of subject confidentiality
US3502182	2020-12-03 (66)	Data Privacy	I01.01: Breach of subject confidentiality
US3502188	2020-12-03 (60)	Data Privacy	I01.01: Breach of subject confidentiality
US3502191	2020-10-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502191	2020-11-04 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3502207	2020-10-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502211	2020-11-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3502214	2020-08-31 (-52)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502216	2020-12-03 (42)	Data Privacy	I01.01: Breach of subject confidentiality
US3512009	2020-09-16 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3512012	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512022	2020-09-15 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-16 (133)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2020-12-23 (140)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512027	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512028	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512032	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512033	2020-12-29 (140)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512033	2020-12-29 (140)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512041	2021-03-03 (204)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3512043	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512055	2020-10-16 (65)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3512069	2020-10-15 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512088	2020-12-22 (130)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512090	2020-12-22 (130)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512092	2020-12-22 (130)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512092	2020-12-22 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3512095	2020-08-20 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3512096	2020-08-20 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3512097	2020-08-20 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3512105	2020-08-20 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3512108	2020-08-20 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-22 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512108	2020-12-22 (125)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-23 (126)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3512126	2020-12-28 (130)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512128	2020-10-26 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512136	2020-12-20 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3512138	2020-08-22 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3512141	2020-12-07 (104)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-29 (157)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3512157	2020-10-09 (45)	Visit Scheduling	P10.01: Onsite visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512158	2021-01-04 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3512165	2021-01-29 (156)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3512176	2020-12-07 (101)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3512180	2020-08-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512187	2020-12-22 (112)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512189	2020-10-04 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512194	2020-12-27 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3512195	2020-10-01 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512197	2020-11-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512208	2020-11-03 (62)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512216	2020-11-16 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512218	2020-12-22 (110)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3512235	2021-02-10 (159)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512242	2021-01-21 (135)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3512281	2020-09-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-22 (91)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512283	2020-12-29 (98)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512286	2020-12-29 (91)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512304	2020-10-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512308	2020-12-21 (61)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512308	2020-12-22 (62)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-13 (84)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3522004	2020-08-06 (1)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (40)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol Study Treatment Admin/Dispense P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3522005	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522007	2020-10-12 (69)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3522008	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-08 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522011	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522015	2021-01-22 (171)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522019	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522021	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-02 (28)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522022	2021-01-07 (155)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3522033	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3522036	2021-01-11 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3522042	2020-08-24 (18)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3522045	2020-10-14 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522049	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522052	2020-09-03 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522069	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-11 (2)	Inv Oversight	I05.01: Lack of PI oversight
US3522071	2020-09-04 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522077	2020-09-10 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522078	2020-09-09 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522081	2020-09-11 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522096	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522099	2021-01-18 (160)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3522105	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-08 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522126	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522127	2020-12-23 (132)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-18 (189)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3522128	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522128	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3522144	2020-09-11 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522150	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522164	2020-09-17 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522176	2020-09-17 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522177	2020-08-18 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522177	2020-08-24 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522184	2020-08-17 (-1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3522192	2020-09-16 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522194	2020-12-15 (120)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (Follow-up)
US3522200	2021-01-22 (157)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522201	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522208	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522211	2021-03-23 (217)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522211	2021-03-23 (217)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3522218	2020-11-28 (102)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-10 (114)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3522233	2020-09-22 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522254	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522255	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522257	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522264	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522269	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-08 (19)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3522304	2020-09-25 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522305	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522307	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522316	2021-02-12 (173)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522317	2021-02-12 (173)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522333	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522335	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522341	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522376	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522377	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522382	2020-09-24 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522386	2020-08-26 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
	2020-09-24 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522389	2020-09-30 (35)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522392	2020-10-12 (47)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3522413	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522419	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522420	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522427	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522429	2020-12-20 (115)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-01 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522436	2020-08-28 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522453	2020-11-19 (81)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3522460	2020-08-31 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-05 (36)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522479	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3522482	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522488	2020-10-04 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522502	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522506	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522514	2020-10-12 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522533	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522541	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522545	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522547	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522552	2020-12-31 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522558	2020-11-10 (69)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3522559	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-19 (170)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3522586	2020-09-04	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3522598	2020-11-12 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522607	2020-09-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522620	2020-11-18 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (100)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522632	2020-09-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3522642	2020-10-27 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-02 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522643	2020-09-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522659	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522660	2020-09-11 (1)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522671	2021-01-05 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-08 (120)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3522672	2020-11-11 (62)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-25 (106)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-06 (118)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-13 (125)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3522680	2020-09-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522693	2020-11-18 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522707	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-18 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522711	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-25 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3522719	2020-11-30 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3532004	2021-01-20 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532006	2021-01-07 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532007	2021-01-13 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532008	2020-08-21 (10)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-12 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532009	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3532010	2021-01-22 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532015	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-19 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3532016	2021-01-21 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532018	2021-01-07 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532020	2020-09-18 (37)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-02 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532021	2021-01-25 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532023	2021-01-12 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532024	2021-01-12 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532031	2021-01-06 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532033	2021-01-21 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532034	2021-01-14 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532039	2021-01-13 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532040	2020-09-15 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-07 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532041	2021-01-07 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532046	2021-01-07 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532047	2021-01-25 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532049	2021-01-07 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532050	2021-01-08 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532051	2021-01-11 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532052	2021-01-06 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532053	2021-01-25 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532057	2021-01-06 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532060	2020-08-18 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-11 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532063	2021-01-13 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532066	2021-01-13 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532068	2021-01-11 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532070	2021-01-07 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532071	2020-09-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-25 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-12 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3532074	2021-01-13 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532076	2021-01-12 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532078	2021-01-11 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532081	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532082	2021-01-06 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532087	2021-01-07 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532088	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532090	2021-01-07 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532091	2021-01-06 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532095	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532103	2021-01-11 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532104	2021-01-11 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532106	2021-01-11 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532107	2021-01-07 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532114	2021-01-12 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532116	2020-09-22 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-21 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532119	2021-01-13 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532120	2021-01-20 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532123	2021-01-22 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532126	2021-01-21 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532129	2021-01-20 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532131	2021-01-11 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532133	2021-02-02 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2021-02-11 (171)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
	2021-03-03 (191)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3532134	2021-01-14 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532138	2021-02-01 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532139	2021-01-12 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532141	2021-01-06 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532144	2021-01-06 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532147	2021-01-08 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532150	2021-01-20 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532153	2020-11-09 (76)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-12 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-17 (176)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3532155	2021-01-13 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-18 (177)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3532156	2021-01-13 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532161	2021-01-07 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532163	2021-01-22 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532165	2021-01-07 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532170	2020-09-06 (11)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-02-02 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532171	2021-01-13 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532173	2021-01-21 (148)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
US3532174	2021-01-11 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532175	2021-01-06 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532176	2021-01-06 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532180	2021-01-22 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532184	2021-01-07 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532187	2021-01-06 (129)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
US3532189	2021-01-07 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532190	2021-01-14 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532191	2021-01-06 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532194	2021-01-12 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532201	2021-01-20 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532203	2020-12-28 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3532206	2021-01-11 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532207	2021-01-11 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532209	2021-01-12 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532211	2021-01-22 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532212	2020-09-16 (15)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-09-28 (27)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-11-24 (84)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-02-02 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532215	2021-01-14 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532218	2021-01-13 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532222	2021-01-12 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532226	2021-02-12 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532227	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532228	2021-01-25 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532229	2021-01-14 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532232	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532237	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532238	2021-01-13 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532239	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532244	2021-01-08 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532246	2021-01-08 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532250	2021-01-11 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532251	2020-12-07 (91)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-16 (100)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-28 (112)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-07 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532253	2021-01-07 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532254	2021-01-12 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532256	2021-01-06 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532260	2020-10-07 (29)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2021-01-14 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532265	2021-01-08 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532269	2021-01-07 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532272	2021-01-25 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532273	2020-11-18 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-24 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532274	2021-01-13 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532275	2021-01-20 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532276	2021-01-06 (119)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532280	2021-01-08 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3542001	2020-09-17 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3542004	2020-08-19 (7)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3542012	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-20 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542015	2020-09-30 (44)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542019	2020-12-25 (130)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542022	2020-09-14 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-27 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3542024	2020-10-22 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542039	2020-09-18 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542043	2020-10-05 (43)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3542047	2020-08-24 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3542056	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3542057	2020-09-30 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-10 (47)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542059	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542061	2020-09-09 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542064	2021-03-15 (202)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542065	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3542066	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3542070	2020-08-30 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542086	2020-09-11 (15)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542088	2020-10-28 (62)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542090	2020-09-04 (8)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
	2020-10-10 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-03 (68)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-12-03 (98)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3542096	2020-11-20 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542098	2020-10-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542102	2020-09-10 (11)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
	2020-11-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542117	2020-09-01 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542128	2020-10-07 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3542130	2020-11-13 (73)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542132	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-15 (136)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3542138	2020-09-10 (8)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
US3542141	2020-09-18 (16)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542152	2020-10-07 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542154	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542156	2020-10-07 (34)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542163	2020-10-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542167	2020-11-13 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-12 (190)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542171	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542172	2020-10-13 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542176	2020-10-05 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542190	2020-11-05 (58)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542197	2020-12-28 (110)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542212	2020-11-24 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3542214	2021-01-22 (134)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3542215	2020-09-27 (17)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-22 (134)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3542231	2020-10-16 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542242	2020-09-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-21 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542251	2020-10-19 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542264	2021-01-29 (134)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542265	2020-10-05 (18)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-02 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-21 (126)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3542266	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3542275	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542287	2021-01-21 (120)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3542295	2020-10-04 (11)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542295	2020-11-08 (46)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542321	2020-11-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-27 (114)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3542324	2020-11-22 (47)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542339	2020-12-23 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542345	2020-11-24 (41)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542353	2020-11-02 (13)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-17 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542357	2020-12-08 (48)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542360	2020-10-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3552002	2020-10-12 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-23 (75)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3552017	2020-08-16 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3552023	2020-12-28 (138)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3552054	2020-09-16 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552057	2020-09-20 (35)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552058	2020-09-21 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552059	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3552067	2020-10-20 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3552076	2020-09-15 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552081	2020-08-18 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552089	2020-08-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-19 (213)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552107	2021-02-25 (190)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552111	2020-08-23 (4)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552114	2020-09-14 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3552115	2021-02-22 (187)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3552129	2020-09-14 (25)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3552153	2020-12-22 (121)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552162	2020-08-31 (7)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552167	2020-08-29 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3552172	2020-12-16 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552213	2020-11-19 (85)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3552223	2020-09-22 (26)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3552232	2020-08-29 (1)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552232	2021-01-26 (151)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552252	2020-10-26 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3552255	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-27 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552270	2020-12-19 (110)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-03 (125)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3552273	2020-11-02 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552273	2021-02-12 (165)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-03-01 (182)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552281	2020-09-07 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3552283	2020-09-29 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552291	2020-11-05 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3552322	2021-03-24 (202)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3552341	2020-09-07 (3)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552365	2020-12-22 (106)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552367	2020-09-13 (6)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552382	2020-10-30 (52)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3552408	2021-01-22 (134)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552411	2020-09-07 (-4)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552413	2020-10-22 (42)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552427	2021-02-16 (156)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552436	2021-01-11 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552468	2020-10-22 (35)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552474	2020-12-26 (99)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552496	2020-12-11 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552530	2020-11-15 (33)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3552533	2020-11-04 (21)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3562001	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3562004	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3562005	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3562015	2020-09-09 (35)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-01-11 (159)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-17 (165)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3562018	2020-10-26 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-22 (228)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3562021	2020-08-12 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3562026	2020-08-28 (18)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3562028	2020-08-17 (7)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3562031	2020-11-05 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562040	2020-12-12 (121)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-04 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3562052	2021-01-12 (148)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3562063	2020-09-17 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3562064	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3562065	2020-09-14 (25)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3562073	2021-01-30 (160)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3562076	2020-12-30 (128)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3562079	2021-02-23 (182)	Study Treatment Randomization	P04.03: Subject enrolled/dosed at two sites
US3562094	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3562119	2021-03-26 (204)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3562136	2020-12-27 (110)	Concomitant Medication Study Treatment Admin/Dispense	P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3562142	2020-09-17 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3562146	2020-09-17 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3562149	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3562150	2020-10-19 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3562177	2020-10-13 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3562195	2020-10-21 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3562212	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562220	2020-10-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-06 (91)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3562232	2020-10-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-17 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3562235	2020-11-25 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-20 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562236	2020-11-19 (31)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572004	2020-08-16 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-19 (3)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-12-14 (120)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
	2021-03-12 (208)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572005	2020-08-19 (3)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-13 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-30 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-18 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572012	2021-01-21 (157)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572015	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572022	2020-09-21 (34)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572023	2021-01-14 (149)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-11 (177)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3572024	2020-09-22 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-12-21 (125)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572029	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572036	2021-01-09 (143)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3572037	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572037	2020-09-22 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-23 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3572038	2020-09-24 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-02 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-04 (77)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3572039	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572042	2020-11-17 (90)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572045	2021-01-18 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572046	2020-08-19 (-1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572046	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572047	2020-09-24 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572062	2021-01-18 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572064	2020-09-04 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-04 (196)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572073	2020-09-22 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-23 (122)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3572074	2020-12-28 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572078	2020-12-21 (120)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572079	2020-08-24 (-1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-11-04 (72)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3572086	2021-01-26 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3572088	2020-09-29 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-05 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572101	2020-09-24 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-20 (87)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572101	2021-01-21 (149)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3572108	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572110	2020-08-26 (-1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-07 (12)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-08 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572111	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572112	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572113	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-11-20 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572114	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-20 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572115	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572119	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572120	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572122	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572124	2020-08-26 (-1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-08-27 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572124	2020-09-25 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572127	2020-08-28 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-19 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3572130	2020-08-28 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-29 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-20 (146)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572132	2020-08-28 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572134	2020-08-28 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572139	2020-08-28 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-11-03 (68)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-15 (110)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-26 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572140	2020-08-28 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572143	2020-08-31 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-11-04 (66)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572145	2020-08-31 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-29 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-02 (94)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-12 (166)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572147	2020-08-31 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-12-24 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572153	2020-08-31 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572156	2020-09-01 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-25 (147)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572157	2020-09-01 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572159	2020-09-01 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572160	2020-09-01 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-05 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-11 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572163	2020-09-01 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-30 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-06 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572165	2020-09-02 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-02 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-10 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572167	2020-09-01 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572167	2020-09-02 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572168	2020-09-02 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572170	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572174	2020-09-03 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-12-23 (112)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
	2021-01-27 (147)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572175	2020-09-03 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572176	2020-09-03 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572181	2020-09-03 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572183	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-05 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572185	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572186	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-03-18 (196)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572187	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-12-04 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572191	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-18 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572192	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572195	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-05 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572198	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-23 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-23 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572199	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-15 (12)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572200	2020-08-28 (-7)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572201	2020-09-03 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-06 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-10 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572201	2020-12-16 (104)	Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days
	2021-02-17 (167)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3572204	2020-09-07 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572205	2021-01-04 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572209	2020-09-07 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-10 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572211	2020-09-07 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-11-09 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572213	2020-09-07 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572214	2020-09-07 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572215	2020-09-08 (2)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572219	2020-09-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-16 (9)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-11-30 (84)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-26 (110)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572222	2020-09-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-03-01 (175)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-09 (183)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572223	2020-09-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-05 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572224	2020-09-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572227	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-11-09 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572229	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-12-30 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572230	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572235	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572236	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572237	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572239	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572240	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572244	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572247	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-14 (127)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3572248	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572249	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-09 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572254	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572256	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-27 (140)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3572258	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-04 (56)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572259	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572262	2020-09-10 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-08 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572265	2020-09-10 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-11 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-12-01 (82)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572266	2020-09-11 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572267	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572268	2020-09-11 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572269	2020-09-11 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572275	2020-09-11 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572280	2020-09-11 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-14 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-10 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572281	2020-09-14 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-04 (52)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3572283	2020-09-14 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572284	2020-09-14 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572288	2020-09-16 (3)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572288	2020-10-14 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572289	2020-09-14 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572290	2020-09-14 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-13 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3572294	2020-09-15 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572296	2020-09-15 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572296	2020-10-16 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572297	2020-09-15 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572298	2020-09-15 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3572301	2020-09-14 (-2)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-16 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2021-01-11 (118)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572305	2020-09-03 (-13)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572305	2020-12-09 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-16 (154)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572306	2020-09-16 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-11-17 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-10 (117)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3572308	2020-09-16 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-18 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572309	2020-11-30 (71)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3572310	2020-12-09 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572323	2020-09-25 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-01-02 (101)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-18 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-25 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-05 (135)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572327	2020-12-12 (79)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3572328	2020-09-17 (-7)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572328	2020-10-27 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572329	2020-09-21 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3572331	2020-09-21 (1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-21 (31)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-06 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572337	2020-10-31 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572339	2020-11-04 (43)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-18 (87)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572342	2020-12-15 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572349	2020-10-30 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-22 (89)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572351	2020-09-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-28 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572352	2020-12-09 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572353	2020-10-03 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-28 (30)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-31 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572353	2021-01-06 (100)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3572354	2020-09-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-02 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572365	2020-11-09 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3572377	2020-11-11 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572380	2020-10-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-13 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-14 (38)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-01-06 (91)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572385	2020-11-17 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572386	2020-10-11 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-11 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-22 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572388	2021-02-02 (114)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-03 (143)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3572392	2020-11-12 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3572394	2020-11-12 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572395	2021-02-10 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572402	2020-11-14 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3572405	2020-10-22 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3572407	2020-10-26 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3572408	2020-11-23 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3582006	2020-09-16 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3582017	2020-08-27 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3582019	2021-02-05 (169)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3582020	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3582024	2020-12-31 (133)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3582026	2020-08-21 (1)	Accidental Unblinding	P12.01: Inadvertent unblinding of site personnel
US3582035	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3582080	2020-10-06 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3582087	2021-03-02 (183)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-22 (203)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3582109	2020-09-18 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3582115	2020-08-20 (-19)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3582116	2021-01-26 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3582142	2020-12-31 (112)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3582144	2020-09-22 (12)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3582145	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3582161	2020-11-20 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3582162	2020-10-28 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3582170	2020-11-30 (60)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3582172	2020-11-23 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3582182	2021-01-02 (83)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3582183	2020-10-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3582184	2020-11-24 (41)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3582190	2020-10-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3592007	2020-08-26 (22)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-27 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-28 (208)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-08 (216)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592007	2021-03-08 (216)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3592027	2020-09-21 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-26 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592029	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3592030	2020-10-21 (76)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-20 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592035	2021-01-26 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592036	2021-01-25 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592042	2021-02-09 (187)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3592046	2021-01-22 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592049	2021-01-18 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592054	2020-12-29 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3592055	2020-08-08 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3592070	2021-01-20 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592071	2020-12-30 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3592075	2021-01-01 (147)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-03 (149)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-05 (182)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3592084	2020-11-03 (87)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-11-10 (94)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-07 (121)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592084	2021-01-28 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592087	2021-01-27 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592090	2021-01-25 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592094	2021-01-21 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592096	2021-01-28 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592097	2021-01-21 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592098	2020-08-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3592101	2021-01-14 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592109	2021-01-19 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592113	2021-01-26 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592114	2021-01-18 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592117	2020-11-06 (88)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3592118	2020-10-21 (72)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592121	2021-01-22 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592126	2021-01-27 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592130	2020-09-15 (35)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
US3592131	2020-10-14 (64)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-26 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592132	2020-11-07 (88)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3592138	2021-01-25 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592139	2021-01-28 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-25 (197)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3592140	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592145	2020-09-25 (44)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592147	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592149	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592150	2021-01-27 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592155	2021-01-29 (169)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-01 (200)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3592156	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3592158	2021-01-19 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592159	2020-12-22 (131)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3592161	2020-11-02 (81)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3592168	2021-01-21 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592175	2021-01-28 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592176	2020-08-21 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-13 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3592183	2020-09-13 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-25 (42)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3592185	2021-01-21 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592187	2021-01-19 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592189	2020-11-12 (90)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3592195	2021-01-27 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592203	2021-01-27 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592206	2021-01-25 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592209	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592210	2021-02-04 (172)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3592212	2021-01-22 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592213	2020-10-07 (52)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-19 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592217	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592218	2020-10-15 (60)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3592224	2020-10-07 (52)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3592225	2021-01-15 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592228	2021-01-19 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592229	2021-01-25 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592233	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592240	2021-01-20 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592243	2021-01-18 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592244	2021-01-18 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592248	2021-01-21 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592252	2021-01-21 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3602001	2021-03-04 (186)	Data Privacy	I01.01: Breach of subject confidentiality
US3602002	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3602006	2021-03-04 (184)	Data Privacy	I01.01: Breach of subject confidentiality
US3602008	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-04 (156)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-04 (184)	Data Privacy	I01.01: Breach of subject confidentiality
US3602009	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602009	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-16 (105)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3602010	2020-10-15 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-03-04 (183)	Data Privacy	I01.01: Breach of subject confidentiality
US3602012	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-04 (183)	Data Privacy	I01.01: Breach of subject confidentiality
US3602014	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3602015	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-04 (183)	Data Privacy	I01.01: Breach of subject confidentiality
US3602021	2021-03-04 (177)	Data Privacy	I01.01: Breach of subject confidentiality
US3602024	2021-03-04 (176)	Data Privacy	I01.01: Breach of subject confidentiality

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602025	2020-10-08 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-03-04 (176)	Data Privacy	I01.01: Breach of subject confidentiality
US3602026	2021-03-04 (176)	Data Privacy	I01.01: Breach of subject confidentiality
US3602029	2020-10-30 (50)	ICF Process/Timing	I02.01: Signed informed consent not available on site
	2021-03-04 (175)	Data Privacy	I01.01: Breach of subject confidentiality
US3602034	2020-10-28 (48)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3602038	2020-10-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-05 (145)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-12 (180)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3602039	2021-03-04 (171)	Data Privacy	I01.01: Breach of subject confidentiality
US3602042	2020-10-20 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602044	2021-03-04 (170)	Data Privacy	I01.01: Breach of subject confidentiality
US3602048	2020-12-30 (105)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3602049	2021-03-04 (169)	Data Privacy	I01.01: Breach of subject confidentiality
US3602051	2021-03-04 (169)	Data Privacy	I01.01: Breach of subject confidentiality
US3602052	2020-10-14 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-04 (169)	Data Privacy	I01.01: Breach of subject confidentiality
US3602054	2020-09-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-20 (34)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-03-04 (169)	Data Privacy	I01.01: Breach of subject confidentiality
US3602058	2021-03-04 (168)	Data Privacy	I01.01: Breach of subject confidentiality
US3602060	2021-01-12 (117)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-08 (144)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-04 (168)	Data Privacy	I01.01: Breach of subject confidentiality

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602065	2020-12-30 (101)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3602066	2021-03-04 (165)	Data Privacy	I01.01: Breach of subject confidentiality
US3602069	2021-03-04 (165)	Data Privacy	I01.01: Breach of subject confidentiality
US3602073	2021-01-05 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3602074	2020-12-05 (76)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-11 (82)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-03-04 (165)	Data Privacy	I01.01: Breach of subject confidentiality
US3602075	2021-01-12 (113)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-09 (141)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality
US3602077	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602080	2020-10-28 (37)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality
US3602083	2020-09-26 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality
US3602084	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality
US3602086	2021-03-04 (164)	Data Privacy	I01.01: Breach of subject confidentiality
US3602088	2021-03-04 (163)	Data Privacy	I01.01: Breach of subject confidentiality
US3602091	2021-03-04 (163)	Data Privacy	I01.01: Breach of subject confidentiality
US3602096	2021-03-04 (162)	Data Privacy	I01.01: Breach of subject confidentiality
US3602097	2021-03-04 (162)	Data Privacy	I01.01: Breach of subject confidentiality
US3602100	2021-03-04 (162)	Data Privacy	I01.01: Breach of subject confidentiality
US3602101	2020-10-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-04 (162)	Data Privacy	I01.01: Breach of subject confidentiality

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602102	2021-03-04 (162)	Data Privacy	I01.01: Breach of subject confidentiality
US3602103	2021-03-04 (151)	Data Privacy	I01.01: Breach of subject confidentiality
US3602105	2021-03-04 (161)	Data Privacy	I01.01: Breach of subject confidentiality
US3602109	2021-03-04 (161)	Data Privacy	I01.01: Breach of subject confidentiality
US3602110	2021-03-04 (158)	Data Privacy	I01.01: Breach of subject confidentiality
US3602111	2020-11-05 (38)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-01-13 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3602112	2021-03-04 (157)	Data Privacy	I01.01: Breach of subject confidentiality
US3602116	2020-10-29 (30)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-24 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-03 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3602117	2021-03-04 (155)	Data Privacy	I01.01: Breach of subject confidentiality

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602118	2020-10-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3602119	2020-12-11 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3602120	2021-03-04 (154)	Data Privacy	I01.01: Breach of subject confidentiality
US3602123	2021-03-04 (154)	Data Privacy	I01.01: Breach of subject confidentiality
US3602128	2021-01-14 (102)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-04 (151)	Data Privacy	I01.01: Breach of subject confidentiality
US3602130	2020-11-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-04 (151)	Data Privacy	I01.01: Breach of subject confidentiality
US3602133	2021-03-04 (150)	Data Privacy	I01.01: Breach of subject confidentiality
US3602135	2021-03-04 (149)	Data Privacy	I01.01: Breach of subject confidentiality
US3602136	2021-03-04 (148)	Data Privacy	I01.01: Breach of subject confidentiality
US3602139	2021-03-04 (134)	Data Privacy	I01.01: Breach of subject confidentiality

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602141	2020-11-08 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-26 (49)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3602143	2021-03-04 (144)	Data Privacy	I01.01: Breach of subject confidentiality
US3602146	2021-03-04 (142)	Data Privacy	I01.01: Breach of subject confidentiality
US3602149	2020-11-16 (33)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-03-04 (141)	Data Privacy	I01.01: Breach of subject confidentiality
US3602152	2021-02-03 (112)	Data Privacy	I01.01: Breach of subject confidentiality
US3602153	2020-10-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-04 (141)	Data Privacy	I01.01: Breach of subject confidentiality
US3602154	2021-03-04 (141)	Data Privacy	I01.01: Breach of subject confidentiality
US3612005	2020-09-01 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3612031	2020-12-28 (110)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-11 (124)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3612037	2020-12-22 (100)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-11 (120)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3612039	2020-09-16 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-24 (192)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3612052	2020-12-18 (85)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-11 (109)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-22 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3612069	2020-11-11 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3612082	2020-12-31 (71)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-11 (82)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3622002	2020-08-18 (9)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622006	2020-08-18 (9)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622007	2020-08-18 (9)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622008	2020-08-18 (9)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622011	2020-08-18 (8)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622012	2020-08-18 (8)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-10-02 (53)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3622017	2020-08-18 (6)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622019	2020-08-18 (6)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622020	2020-08-18 (6)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622021	2020-08-18 (6)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622022	2020-08-18 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622025	2020-08-18 (5)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622026	2020-08-18 (5)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622027	2020-08-18 (5)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622031	2020-08-18 (5)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622032	2020-08-18 (2)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622034	2020-08-18 (2)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622036	2020-08-18 (2)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622037	2020-08-18 (2)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3622061	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3622066	2020-11-20 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-07 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3622067	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622087	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622093	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622099	2020-11-12 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622101	2020-09-26 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622102	2020-09-26 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622116	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622130	2021-01-19 (140)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3622142	2021-02-02 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-02-07 (158)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3622145	2020-10-23 (51)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3622150	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622150	2020-10-02 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-04 (62)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3622161	2020-09-05 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3622179	2020-11-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622189	2020-10-12 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622194	2021-01-20 (127)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622194	2021-01-20 (127)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3622199	2020-12-01 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622209	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3622210	2020-09-21 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-18 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622212	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3622214	2020-09-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622214	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622238	2020-11-11 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3622247	2020-12-03 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622253	2020-11-01 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622257	2020-11-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622271	2020-11-18 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3622280	2020-10-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-15 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622282	2020-12-08 (49)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3622288	2020-11-19 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-16 (55)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632002	2021-01-17 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3632007	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-28 (157)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632017	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3632018	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632018	2020-12-24 (120)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-25 (121)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-29 (125)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-31 (127)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-01 (128)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-22 (149)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632025	2020-12-24 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3632046	2021-01-04 (124)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-02-02 (153)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3632054	2021-01-11 (126)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632054	2021-03-24 (198)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632068	2020-10-05 (26)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632075	2020-10-13 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3632076	2020-10-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3632090	2020-11-24 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3632097	2020-10-14 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3632102	2020-11-20 (60)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632107	2020-11-26 (64)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632114	2020-12-24 (80)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-25 (81)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-15 (102)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632117	2021-01-06 (92)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3632127	2020-12-09 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3632129	2020-11-19 (37)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3632134	2020-12-24 (71)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-25 (72)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-31 (78)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632134	2021-01-01 (79)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-07 (85)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3632150	2020-10-21 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3632152	2020-12-24 (63)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-25 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-28 (67)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-31 (70)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-01 (71)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-07 (77)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-22 (92)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632154	2020-11-19 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-12-24 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-25 (65)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-30 (70)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3642001	2021-01-08 (142)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642003	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-08 (141)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642004	2021-01-08 (141)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642006	2021-01-08 (140)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642009	2021-01-08 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642011	2020-08-25 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (137)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642012	2020-08-25 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (137)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642013	2020-08-26 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642015	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642018	2020-08-20 (-6)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642018	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642023	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642024	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-30 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642025	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642029	2020-08-26 (-1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-19 (146)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642029	2021-01-19 (146)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-02-27 (185)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642031	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642035	2020-08-27 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642038	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642039	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642040	2020-08-28 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642040	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642042	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642043	2020-08-29 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642046	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642050	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642051	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642052	2020-08-29 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642052	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642053	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642054	2020-08-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642057	2020-10-30 (63)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642058	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642060	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642065	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642066	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642068	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642071	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642074	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642076	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642078	2020-08-31 (-1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642078	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642079	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642081	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642083	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642085	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642086	2020-09-01 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-02 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642087	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-21 (142)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642091	2020-09-03 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642093	2020-09-02 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642094	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642097	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642100	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642101	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642102	2020-09-01 (-3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642104	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642107	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642109	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642113	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642115	2020-09-04 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3642116	2020-09-04 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642118	2020-09-04 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642120	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642122	2020-09-05 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642124	2020-10-31 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3642126	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642129	2020-09-04 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642130	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642131	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642132	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642135	2021-01-08 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642137	2021-01-08 (123)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642139	2021-01-08 (123)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642143	2021-01-08 (123)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642144	2021-01-08 (123)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642146	2021-01-08 (123)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642147	2021-01-08 (122)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642147	2021-01-21 (135)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642151	2021-01-08 (122)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642152	2020-12-23 (106)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642155	2021-01-08 (122)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642158	2021-01-08 (121)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642160	2020-12-18 (100)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642162	2021-01-08 (121)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642163	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (121)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642166	2021-01-08 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642167	2021-01-08 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642169	2020-10-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-08 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642170	2021-01-08 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642174	2021-01-08 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642175	2020-12-19 (99)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642178	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642179	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642181	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642182	2020-08-26 (-17)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642184	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642185	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642189	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642191	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642193	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642195	2020-08-26 (-17)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642196	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642197	2020-09-11 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-08 (119)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642202	2020-11-08 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-08 (117)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642205	2020-09-13 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (117)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642211	2020-12-21 (99)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642212	2020-12-22 (100)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-08 (117)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642213	2021-01-08 (117)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642216	2020-12-30 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642222	2021-01-08 (116)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642223	2021-01-08 (115)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642224	2020-09-15 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-16 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-08 (115)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642227	2021-01-08 (115)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642229	2020-08-26 (-21)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (115)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642231	2021-01-08 (114)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-27 (133)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3642233	2021-01-08 (114)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642236	2020-09-17 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (114)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642237	2021-01-05 (110)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642238	2021-01-08 (113)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642241	2021-01-08 (113)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-23 (128)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642242	2021-01-08 (113)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642244	2020-09-18 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (113)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642249	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642251	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642252	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-23 (127)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642253	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642256	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642257	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642259	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642261	2020-12-27 (100)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642262	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642264	2020-09-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642265	2020-09-19 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-09 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642266	2021-01-08 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642270	2020-09-21 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3642274	2021-01-08 (106)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642278	2021-01-06 (103)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642279	2021-01-08 (105)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642281	2021-01-08 (105)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-03-09 (165)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642282	2021-01-08 (105)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642283	2020-12-30 (94)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642287	2021-01-08 (101)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642289	2021-01-08 (101)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642290	2020-12-29 (90)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642298	2020-11-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-03 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642299	2020-11-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3642300	2020-10-02 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642300	2020-12-26 (85)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642305	2020-10-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-10 (34)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-23 (108)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642310	2021-01-07 (88)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642313	2020-11-12 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-09 (89)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642314	2020-10-12 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3642331	2020-10-20 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642342	2020-10-22 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3652003	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-02 (97)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3652004	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3652014	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3652020	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3652025	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-12 (148)	Study Treatment Admin/Dispense	P05.14: Subject was dosed with expired IP (Open Label)
US3652029	2021-02-12 (148)	Study Treatment Admin/Dispense	P05.14: Subject was dosed with expired IP (Open Label)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3652032	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-23 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3652039	2020-11-06 (39)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3652040	2021-02-12 (135)	Study Treatment Admin/Dispense	P05.14: Subject was dosed with expired IP (Open Label)
US3652041	2020-09-28 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-26 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-15 (110)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-12 (138)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
		Study Treatment Admin/Dispense	P05.14: Subject was dosed with expired IP (Open Label)
US3652042	2020-09-30 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3652044	2021-03-03 (154)	Study Treatment Admin/Dispense	P05.14: Subject was dosed with expired IP (Open Label)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3652054	2021-02-12 (117)	Study Treatment Admin/Dispense	P05.14: Subject was dosed with expired IP (Open Label)
US3652058	2020-12-08 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3662001	2020-09-12 (4)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-19 (133)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662010	2020-09-22 (13)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662017	2020-10-13 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3662023	2021-01-08 (115)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3662025	2020-11-12 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662041	2020-12-29 (113)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-28 (143)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3662045	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3662054	2020-10-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3662057	2020-12-15 (90)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3662076	2021-01-06 (119)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662083	2020-09-10 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3662088	2021-02-19 (159)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662089	2020-09-27 (14)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662090	2020-10-27 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3662093	2020-11-16 (64)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662095	2020-10-22 (38)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-10 (57)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662096	2020-09-22 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662098	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-14 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-30 (46)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-11 (58)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662103	2020-11-10 (56)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662106	2020-10-14 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3662123	2020-09-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-03 (136)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3662124	2021-01-09 (111)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-11 (113)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-02-03 (136)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3662125	2020-10-01 (10)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3662133	2020-10-21 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3662136	2021-01-08 (106)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662142	2020-09-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-29 (124)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3662156	2020-12-03 (60)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3662159	2020-10-21 (14)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3662175	2020-12-15 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3662180	2020-10-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-25 (35)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662181	2020-10-26 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3672001	2021-01-15 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672004	2021-02-01 (180)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672005	2021-01-26 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672006	2021-01-15 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672012	2021-01-25 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672013	2020-09-09 (35)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3672014	2021-01-29 (177)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672018	2021-02-22 (200)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3672021	2021-01-15 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672023	2021-01-26 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672025	2021-01-26 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672027	2021-01-27 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672029	2021-02-03 (178)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672032	2021-01-18 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672033	2021-01-15 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672038	2021-01-26 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672040	2021-01-27 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672043	2021-01-15 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672044	2021-01-15 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672047	2020-10-23 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-15 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672050	2021-01-15 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672053	2020-09-14 (35)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3672054	2021-01-27 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672058	2021-01-26 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672060	2021-01-15 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672062	2021-01-28 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672066	2021-01-15 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672068	2021-01-27 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672070	2021-01-27 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672071	2021-01-27 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672076	2021-01-15 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672078	2021-01-29 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672079	2021-01-15 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672081	2021-01-18 (160) 2021-03-22 (223)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3672084	2021-01-31 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672086	2021-01-22 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672091	2021-01-26 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672095	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672097	2020-10-09 (58)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-02-01 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672099	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672102	2021-01-26 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672104	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672107	2021-01-25 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672111	2021-01-28 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672113	2021-01-27 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672116	2021-01-31 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672124	2021-01-18 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672126	2021-01-25 (165)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-08 (179)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3672128	2020-12-18 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672132	2021-01-18 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672133	2021-01-18 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672137	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672139	2021-01-27 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672141	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672143	2021-01-27 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672144	2021-01-18 (155)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3672146	2021-01-13 (150)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-27 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-24 (192)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-26 (222)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3672151	2020-09-17 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3672155	2021-01-26 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672156	2021-01-27 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672157	2021-01-29 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672160	2021-01-20 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672161	2021-01-26 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672164	2021-01-27 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672165	2021-01-19 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672166	2020-10-23 (67)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-22 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672170	2021-01-20 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672175	2021-01-27 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672179	2020-12-07 (112)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-28 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672180	2021-01-29 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672182	2021-01-19 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672185	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672187	2020-09-18 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-25 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672188	2021-01-29 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672191	2021-01-22 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672194	2021-01-27 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672196	2021-01-27 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672198	2021-01-26 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672199	2021-01-19 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672201	2021-01-28 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672207	2020-12-07 (111)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3672213	2021-01-28 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672214	2021-01-20 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672215	2021-01-20 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672215	2021-01-20 (154)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3672216	2021-01-28 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672219	2020-12-30 (133)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3672222	2020-09-16 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-19 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-21 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672223	2021-01-20 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672225	2020-09-23 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-18 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672228	2021-01-28 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672231	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672232	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672233	2020-09-22 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-27 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672234	2020-12-18 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672238	2020-09-21 (33)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3672243	2021-01-29 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672244	2021-01-26 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672250	2021-01-25 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672254	2021-01-27 (160)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3672256	2021-01-29 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672257	2021-01-15 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672260	2021-01-26 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672262	2021-01-20 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672263	2021-01-18 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672265	2021-01-20 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672268	2021-01-27 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672269	2021-01-29 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672272	2021-01-29 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672273	2021-01-25 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672277	2021-01-19 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672278	2020-10-01 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-26 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672283	2021-01-25 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672288	2021-01-29 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672290	2021-01-21 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672291	2021-01-29 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672292	2021-01-18 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672297	2021-01-29 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672300	2020-10-02 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-23 (60)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-19 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672305	2020-11-10 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3672306	2021-01-29 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672307	2021-01-25 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672308	2021-01-28 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672310	2021-01-20 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672311	2021-01-26 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672312	2021-02-08 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672313	2020-11-13 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-22 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672320	2021-01-18 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672321	2021-01-29 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672323	2021-01-18 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672324	2021-01-22 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672326	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672329	2021-01-31 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672332	2020-12-11 (101)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-21 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3672333	2020-09-23 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672335	2020-09-24 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-17 (114)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3672337	2021-01-18 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672339	2021-01-29 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672342	2021-01-28 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672345	2021-01-18 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672347	2021-01-21 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672348	2021-01-29 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672350	2021-01-18 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672357	2020-10-23 (58)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3672358	2020-09-28 (33)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-20 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672361	2021-01-28 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672362	2021-01-18 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672367	2021-01-31 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672372	2021-02-10 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672373	2021-01-27 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672374	2021-01-19 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672376	2021-02-03 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672380	2020-10-01 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-11-05 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-31 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672381	2021-02-19 (176)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3672383	2021-01-19 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672385	2020-10-19 (50)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-28 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672387	2021-01-21 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672391	2021-01-25 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672397	2020-11-06 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-19 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672399	2021-01-20 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672402	2020-12-18 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672405	2020-10-07 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-28 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672407	2020-09-29 (27)	Study Procedures/Assessments	P08.07: Subject was not instructed/reminded to report solicited ARs in eDiary after each dosing visit (Day 1 and Day 29)
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-28 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672410	2021-01-31 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672412	2021-01-20 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3682009	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-25 (154)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-28 (157)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3682011	2021-02-01 (161)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3682015	2020-12-24 (121)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-12-29 (126)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3682018	2020-12-15 (112)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3682022	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-23 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-21 (148)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-25 (152)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-02-10 (168)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3682033	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3682040	2020-08-31 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3682040	2020-09-29 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-28 (119)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3682059	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3682070	2020-11-24 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3682072	2020-10-06 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682080	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3682082	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3682086	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3682086	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3682088	2020-12-04 (85)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3682101	2021-01-18 (127)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-19 (128)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-03-15 (183)	Study Procedures/Assessments	P08.07: Subject was not instructed/reminded to report solicited ARs in eDiary after each dosing visit (Day 1 and Day 29)
US3682132	2020-11-19 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3682139	2020-09-04 (~13)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-17 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3682153	2020-12-15 (86)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3682165	2020-10-22 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682179	2021-01-06 (97)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-01-14 (105)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3682180	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-21 (81)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-01-07 (98)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3682189	2020-10-07 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3682198	2020-11-10 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692010	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-30 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-17 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3692013	2020-08-27 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692024	2020-08-31 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692034	2020-09-01 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692042	2020-09-02 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692059	2021-01-07 (125)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3692074	2020-09-07 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692082	2020-09-08 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692085	2020-09-09 (-3)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692088	2020-10-16 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3692093	2020-09-10 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692094	2020-09-10 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692099	2020-09-10 (-8)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692107	2020-12-30 (111)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3692111	2020-09-11 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692114	2020-11-18 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692114	2020-12-31 (109)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3692117	2020-09-13 (-3)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692118	2021-01-07 (116)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3692138	2021-03-15 (179)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3692141	2020-09-21 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692154	2020-09-22 (-3)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-22 (28)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-01 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3692165	2020-09-24 (-4)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692166	2020-10-06 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692169	2021-03-11 (165)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3692176	2020-10-05 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692183	2020-10-30 (22)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3692189	2020-12-18 (68)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3702001	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3702002	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-08 (137)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3702007	2020-10-05 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3702017	2020-09-11 (1)	Concomitant Medication Missing Endpoint Assessments	P09.01: Prohibited concomitant medication or vaccine received by subject P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3702025	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3702035	2020-09-17	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3702040	2020-09-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3702042	2020-10-20 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3702044	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3702053	2020-10-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3702092	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-20 (91)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-02-04 (106)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3712002	2021-02-02 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712004	2020-09-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-03 (57)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-10 (94)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-28 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712009	2021-01-01 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712010	2020-12-17 (100)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712013	2020-09-21 (14)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-26 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712015	2020-12-23 (106)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3712016	2021-02-16 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-11 (183)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3712020	2020-12-08 (91)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712022	2021-02-01 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712025	2021-01-05 (118)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712025	2021-01-05 (118)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-02-16 (160)	Missing Endpoint Assessments Visit Scheduling	P07.07: Saliva sample not collected when required per protocol P10.01: Onsite Visits not performed or out of window
US3712030	2021-02-17 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712033	2021-01-26 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712036	2021-02-03 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712038	2021-03-03 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712047	2021-02-03 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712052	2021-02-01 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712056	2020-10-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-17 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712059	2020-12-02 (66)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
	2021-01-08 (103)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-20 (115)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-25 (120)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-18 (144)	ICF Process/Timing Missing Endpoint Assessments Visit Scheduling	I02.02: Wrong informed consent version signed P07.07: Saliva sample not collected when required per protocol P10.01: Onsite Visits not performed or out of window
US3712060	2020-10-13 (29)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-23 (70)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
	2021-01-28 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712067	2020-10-26 (42)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712070	2021-02-22 (159)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712072	2021-01-27 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712074	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-26 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712076	2021-02-17 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712078	2020-12-28 (103)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712079	2021-01-26 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712084	2021-01-26 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712086	2021-02-03 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712087	2021-01-29 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712088	2021-01-14 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712089	2021-02-19 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712092	2021-01-27 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712094	2021-02-23 (156)	Data Privacy	I01.01: Breach of subject confidentiality
	2021-02-25 (158)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3712096	2020-12-07 (82)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-16 (91)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-17 (92)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-18 (93)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-15 (121)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-29 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712100	2021-02-02 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712103	2021-02-01 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712106	2020-10-08 (15)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712111	2021-01-05 (106)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712114	2020-10-01 (8)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-01 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712115	2021-02-03 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712116	2021-01-29 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712117	2021-01-26 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712122	2021-01-14 (115)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712123	2020-12-11 (75)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3712124	2020-10-08 (16)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-28 (97)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712125	2020-10-07 (13)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-02-19 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712129	2021-01-11 (110)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-13 (112)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-15 (114)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-18 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-25 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-10 (140)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-19 (149)	Visit Scheduling ICF Process/Timing	P10.01: Onsite Visits not performed or out of window I02.03: Informed consent not signed and/or dated by subject
US3712131	2020-12-23 (91)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712133	2021-02-17 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712134	2021-01-14 (116)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712136	2020-11-23 (64)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
	2020-12-22 (93)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3712140	2020-11-09 (46)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3712141	2020-10-02 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-12 (18)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-02-01 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712142	2021-01-28 (128)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3712143	2021-02-04 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-22 (181)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3712144	2021-01-14 (115)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712150	2021-01-07 (106)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712150	2021-01-07 (106)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-12 (111)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-19 (149)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3712156	2021-01-27 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712158	2021-01-27 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712159	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-21 (30)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-10 (50)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-18 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-04 (164)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3712161	2021-02-02 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712164	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712169	2021-01-29 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712174	2020-10-23 (9)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-26 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712175	2021-01-27 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712183	2021-01-29 (107)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712184	2021-02-05 (108)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712187	2021-02-01 (102)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712191	2020-10-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-27 (105)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712194	2020-11-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712195	2021-02-17 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712197	2020-12-22 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3712201	2021-02-05 (113)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712207	2021-01-05 (83)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3712208	2020-11-04 (20)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-03 (111)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712220	2021-01-08 (81)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712222	2021-02-03 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712226	2021-01-26 (97)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712228	2021-01-14 (86)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712230	2020-10-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712230	2020-11-23 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-10 (111)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-23 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712233	2021-02-24 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712234	2020-11-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-11 (82)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712235	2020-12-21 (61)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3712242	2021-01-27 (100)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712244	2021-02-02 (107)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712247	2021-01-22 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3712248	2021-02-23 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712254	2020-11-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3712260	2020-10-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-23 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712263	2020-11-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (57)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-29 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712271	2020-12-14 (54)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-17 (57)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-20 (91)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-24 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712276	2021-02-23 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712278	2021-01-03 (74)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-23 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712291	2020-10-30 (8)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
	2020-11-23 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3712297	2021-02-02 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712300	2021-01-02 (72)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-28 (98)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712304	2021-01-15 (85)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-23 (93)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-25 (95)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712304	2021-01-26 (96)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-27 (97)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-28 (98)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-02-04 (105)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3712306	2021-01-26 (96)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712307	2021-01-11 (81)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712308	2021-01-12 (82)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-13 (83)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-15 (85)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712308	2021-01-20 (90)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-25 (95)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-19 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3722001	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722002	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722004	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722006	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-26 (119)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722006	2020-12-01 (124)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3722012	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722013	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722014	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722017	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722019	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722027	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722032	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722035	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722037	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722043	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-10 (192)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722048	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722053	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722060	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-13 (164)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722061	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722064	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-07 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722066	2020-11-16 (106)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3722067	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722071	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722075	2021-02-02 (183)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722082	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-22 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722083	2021-01-12 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722085	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-01 (151)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722088	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722095	2020-12-03 (121)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3722099	2021-01-08 (157)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722107	2020-12-11 (129)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-04 (153)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3722112	2021-01-13 (162)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722116	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-04 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-05 (184)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722135	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722142	2021-01-07 (154)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722143	2021-01-13 (160)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722150	2020-12-17 (133)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-01-17 (164)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722154	2021-01-12 (159)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-18 (165)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722160	2021-01-18 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722170	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722188	2020-08-11 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3722196	2020-09-04 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-24 (198)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722199	2021-03-22 (223)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3722202	2021-01-14 (156)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722204	2021-01-13 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722211	2020-12-28 (139)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-01 (143)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3722217	2021-02-26 (199)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722220	2020-09-22 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3722228	2021-01-08 (149)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722237	2020-09-10 (29)	Study Treatment Admin/Dispense	P05.07: Subsequent vaccine administered while contraindicated for a visit (e.g.: Pre-Vaccination Body Temperature =38.0°C/100.4°F)
US3722245	2020-09-13 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722251	2020-09-12 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722255	2021-03-14 (213)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722260	2021-02-01 (172)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722264	2021-01-12 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722271	2020-08-18 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3722275	2021-01-05 (144)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722280	2020-09-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722283	2020-09-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722286	2020-09-17 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722298	2021-01-13 (148)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722316	2020-08-23 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-16 (210)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722319	2020-09-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722322	2020-09-24 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3722327	2020-09-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722347	2020-12-29 (131)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-06 (139)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-28 (161)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722351	2021-01-07 (137)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722354	2021-01-08 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722361	2020-09-24 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722369	2021-01-08 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722401	2021-01-05 (133)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722402	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722405	2020-09-29 (33)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-11-04 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-11 (137)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722413	2020-10-22 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-02-01 (145)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722424	2020-09-18 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722427	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3722431	2020-10-01 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-03-17 (168)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722432	2020-10-07 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-05 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3732013	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732015	2020-09-02 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3732016	2021-01-28 (176)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-25 (204)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3732019	2020-12-17 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732032	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732036	2020-12-26 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732049	2020-09-30 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732052	2020-09-22 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732061	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732063	2020-08-13 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3732088	2020-08-23 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3732091	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3732101	2020-09-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-21 (125)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732107	2020-12-21 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732110	2020-08-23 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-28 (9)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
	2021-01-24 (158)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732117	2020-09-17 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-10-02 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3732120	2020-09-17 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732126	2020-09-18 (29)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732140	2020-11-23 (92)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3732144	2020-09-21 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732145	2020-12-22 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732153	2020-10-01 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732156	2020-12-22 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732172	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732174	2020-12-21 (118)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-02 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3732176	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-19 (86)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732177	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732196	2020-10-02 (37)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3732207	2020-09-20 (25)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-09-22 (27)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-23 (28)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3732210	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732223	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732265	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732266	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732273	2020-12-02 (91)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732280	2021-01-21 (140)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3732281	2020-09-04 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown
	2020-10-06 (33)	Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown
	2020-10-22 (49)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732292	2020-10-06 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732296	2020-09-09 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3732298	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2020-10-14 (36)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732303	2020-12-31 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732304	2020-09-09 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown
	2020-10-07 (29)	Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown
	2020-12-03 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732306	2020-11-24 (77)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3732312	2020-10-01 (21)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-09 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3732323	2020-10-19 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732326	2020-09-21 (7)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-06 (22)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732328	2020-09-14 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2020-10-12 (29)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
US3732331	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732337	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-11 (58)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3732339	2020-09-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732341	2020-11-11 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732343	2020-10-22 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732345	2020-09-14	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3732346	2020-09-15 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-10-13 (29)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3732371	2020-11-08 (47)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-08 (108)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-13 (113)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3732374	2020-10-21 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732383	2020-11-09 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732389	2020-10-07 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3732392	2020-11-13 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732398	2020-10-19 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-27 (40)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732401	2021-01-17 (89)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-19 (91)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-21 (93)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3742002	2020-09-13 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3742008	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742044	2020-09-19 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742047	2020-08-21 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742067	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742068	2021-01-11 (138)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3742107	2020-10-06 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3742108	2021-02-03 (162)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742118	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3742120	2020-08-31 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742123	2020-10-07 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742215	2020-11-10 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742216	2020-09-23 (22)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3742225	2020-10-28 (56)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3742271	2021-03-02 (179)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742284	2020-10-14 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-20 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742301	2020-10-08 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-14 (128)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742320	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742353	2020-09-16 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742358	2020-09-16 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-19 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-07 (82)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3742364	2020-09-16 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-19 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742373	2020-11-16 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742384	2020-09-15 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742392	2020-09-15 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742392	2020-11-24 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742395	2020-09-16 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742398	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3742424	2020-10-17 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3742456	2020-09-21 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3752003	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752005	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752007	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752007	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3752012	2020-08-06 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-23 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3752014	2020-08-06 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752015	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3752021	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752021	2020-12-23 (136)	Concomitant Medication Study Treatment Admin/Dispense	P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752025	2020-08-10 (1)	ICF Process/Timing Study Treatment Admin/Dispense	I02.04: Informed consent not signed and/or dated by appropriate site staff P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3752027	2020-10-12 (64) 2020-12-17 (130)	Study Treatment Admin/Dispense Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation P05.09: Participant received less than 2 doses of IP during the study participation
US3752029	2020-08-10 (1) 2020-12-22 (135) 2021-01-05 (149)	Study Treatment Randomization Study Treatment Admin/Dispense Concomitant Medication	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum) P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study P09.01: Prohibited concomitant medication or vaccine received by subject
US3752030	2020-12-15 (128)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752030	2020-12-15 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752033	2020-08-10 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752039	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752042	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3752043	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752045	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752053	2020-12-17 (128)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3752065	2020-09-08 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752073	2021-01-06 (147)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752073	2021-01-06 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752078	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752083	2020-12-06 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752090	2020-09-04 (22)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-16 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3752096	2020-09-17 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752097	2021-02-08 (179)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3752100	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752114	2020-09-04 (19)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-12 (57)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-17 (123)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3752115	2020-08-17 (1)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3752117	2020-12-04 (110)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-03-01 (197)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3752157	2020-12-16 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752160	2021-01-05 (140)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752161	2020-10-21 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752162	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-23 (66)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-25 (68)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-27 (70)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3752167	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752175	2020-09-16 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752177	2020-09-21 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3752179	2020-09-21 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752193	2020-12-16 (118)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752194	2021-01-04 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752196	2021-01-06 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752197	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752198	2021-01-07 (140)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752209	2020-12-28 (130)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752213	2021-01-01 (134)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-17 (150)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752229	2020-12-16 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752232	2020-08-23 (-1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3752240	2020-12-17 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752241	2020-12-21 (119)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752249	2020-12-17 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752259	2021-01-12 (140)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752261	2020-12-17 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752262	2020-12-23 (120)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752269	2020-09-25 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-31 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-04 (163)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3752270	2020-12-27 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752271	2020-09-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3752277	2021-01-06 (133)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752280	2021-03-12 (198)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752284	2020-09-29 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3752299	2020-12-04 (99)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3752300	2020-11-17 (82)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752304	2021-03-12 (197)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752308	2020-08-27 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3752319	2020-12-15 (107)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3752321	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752322	2020-09-29 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-24 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-29 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752324	2020-12-22 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752325	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752331	2020-10-12 (42)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-17 (108)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3752338	2020-12-18 (109)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752344	2020-11-16 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752344	2021-01-20 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752366	2020-09-10 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3752367	2020-09-28 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3752372	2021-02-10 (161)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752396	2021-02-01 (151)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3752415	2020-12-17 (105)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752418	2020-12-28 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752422	2020-12-22 (105)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3762002	2020-08-20 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3762029	2020-09-21 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3762037	2020-11-04 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762040	2020-09-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3762044	2021-01-07 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3762061	2021-01-13 (141)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3762097	2020-09-26 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3762112	2021-01-05 (128)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3762119	2020-10-04 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3762122	2020-12-28 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3762123	2020-11-06 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762124	2020-11-03 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762126	2020-09-01 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3762153	2020-11-06 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3762169	2020-10-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3762174	2020-10-06 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3762248	2020-09-12 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3762249	2020-09-16 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3762251	2021-01-13 (125)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3762253	2020-10-09 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3762260	2020-09-18 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3762272	2020-10-15 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3762277	2020-11-18 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3772004	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-31 (28)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-11-10 (99)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-12-08 (127)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-02-04 (185)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3772007	2021-02-09 (189)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3772009	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-05 (185)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772009	2021-02-05 (185)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772010	2020-09-07 (34)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
	2021-01-05 (154)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error
	2021-02-11 (191)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772014	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3772019	2021-02-04 (183)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772023	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772025	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772025	2020-09-30 (56)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-06 (62)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3772026	2020-09-10 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (126)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-12-16 (133)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-18 (135)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-19 (136)	Inv Record Keeping Source Docs	I10.01: Persistent inadequate source documents after re-education
	2021-01-24 (172)	Inv Record Keeping Source Docs	I10.01: Persistent inadequate source documents after re-education
US3772032	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772035	2020-11-20 (103)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772035	2020-11-30 (113)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772036	2021-02-05 (179)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772042	2020-09-14 (35)	Inv Oversight	I05.01: Lack of PI oversight
	2021-02-05 (179)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772047	2020-12-08 (120)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-12-11 (123)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3772048	2020-09-09 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3772051	2020-09-23 (43)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3772053	2021-02-05 (178)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772053	2021-02-05 (178)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772072	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772073	2021-02-04 (175)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772074	2020-08-14 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772082	2020-09-14 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3772086	2020-09-10 (25)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3772090	2020-11-21 (96)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-24 (129)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-03 (139)	Inv Record Keeping Source Docs	I10.01: Persistent inadequate source documents after re-education

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772095	2020-12-07 (111)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-12-29 (133)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-21 (156)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3772102	2020-08-20 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772106	2020-08-20 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772111	2020-08-28 (8)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-09 (50)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3772121	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772125	2021-02-04 (168)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772125	2021-02-04 (168)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772131	2020-08-22 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-03-02 (193)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3772141	2021-03-09 (198)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3772151	2020-09-22 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3772152	2021-02-04 (162)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772153	2020-10-15 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-23 (89)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-29 (125)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-24 (151)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772153	2021-02-03 (161)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3772154	2020-10-15 (50)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-20 (55)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3772157	2020-11-09 (75)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3772159	2020-12-03 (99)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-12-12 (108)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-21 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3772162	2020-12-12 (108)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-18 (145)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-21 (148)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3772166	2021-02-23 (180)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772168	2020-11-17 (82)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-04 (161)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772175	2021-02-05 (162)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772176	2020-08-27 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772179	2021-01-08 (134)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3772182	2020-11-13 (75)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-11-18 (80)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3772184	2020-11-19 (81)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2021-02-04 (158)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772184	2021-02-04 (158)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772186	2021-01-08 (131)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2021-02-05 (159)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772201	2021-02-05 (157)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2021-03-14 (194)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3772208	2020-10-14 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-18 (77)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3772209	2020-11-03 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3772220	2021-02-04 (155)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772226	2021-02-04 (155)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772226	2021-02-04 (155)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772230	2020-09-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772234	2021-02-04 (153)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3772235	2021-02-16 (160)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772242	2021-02-04 (148)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2021-02-05 (149)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772246	2020-11-11 (63)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772252	2020-10-21 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-02-02 (145)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772256	2021-02-05 (148)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3772264	2021-02-05 (148)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3772271	2020-09-17 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-02-04 (141)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2021-03-13 (178)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3772272	2020-09-18 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772281	2021-03-03 (161)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3772285	2020-11-23 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772285	2021-02-05 (117)	ICF Process/Timing Inv Communication with Ethics	I02.05: Informed consent not signed prior to any study procedure I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
US3782010	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3782014	2021-03-10 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3782050	2020-08-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3782053	2020-08-19 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3782109	2020-08-28 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3782161	2020-11-06 (60)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-02-01 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-03-22 (196)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3782164	2020-11-01 (54)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3792004	2020-08-14 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3792013	2020-11-04 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-12-31 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3792021	2020-12-26 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3792026	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3792033	2020-10-05 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3792038	2021-02-11 (161)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3792050	2021-01-22 (131)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3792052	2020-10-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3792055	2020-10-26 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3792056	2020-09-16 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3792070	2020-10-21 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3792073	2020-10-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3792078	2020-12-27 (90)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3792079	2020-10-29 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-26 (151)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3792086	2020-10-05 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3792088	2021-01-11 (98)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3802009	2021-01-05 (140)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3802010	2020-08-19 (1)	Missing Endpoint Assessments	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2020-08-26 (8)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3802012	2020-11-04 (78)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802013	2020-09-16 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802015	2021-03-17 (210)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3802023	2020-08-28 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802024	2020-12-23 (122)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3802029	2020-09-18 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3802038	2020-09-22 (28)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802050	2020-08-26 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3802057	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802078	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3802086	2020-09-01	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3802101	2020-09-02	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3802114	2020-09-01 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802120	2021-03-08 (187)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3802127	2020-10-30 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802138	2020-10-29 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802144	2020-09-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3802151	2021-01-06 (122)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-04 (151)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3802155	2020-10-08 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802175	2020-10-09 (32)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3802185	2020-11-11 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802194	2020-10-01 (22)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802199	2020-09-09 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802199	2020-10-07 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-07 (120)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3802204	2020-12-28 (110)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-12-30 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3802210	2020-12-21 (103)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3802219	2020-12-23 (104)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802222	2020-09-11	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3802227	2020-09-18 (8)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802230	2020-09-14 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3802231	2020-12-30 (108)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802234	2021-01-11 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3802242	2020-09-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802260	2020-09-18 (4)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802261	2020-11-12 (59)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3812011	2020-08-09 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812018	2020-12-18 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3812020	2020-08-11 (9)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3812024	2020-08-10 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3812041	2020-10-15 (72)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3812061	2020-08-05 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3812068	2020-08-06 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3812079	2020-12-31 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812109	2020-09-04 (26)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3812124	2020-08-13 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (35)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-30 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812137	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3812150	2020-12-28 (139)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3812155	2020-08-20 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812174	2020-09-10 (28)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-09-11 (29)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812174	2021-02-19 (190)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3812175	2020-10-16 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812188	2020-08-15 (1) 2021-02-19 (189)	ICF Process/Timing ICF Process/Timing	I02.02: Wrong informed consent version signed I02.02: Wrong informed consent version signed
US3812189	2020-09-16 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3812197	2020-09-01 (16) 2020-10-14 (59)	Inv Safety Rptg (Reg/Sponsor) Study Treatment Admin/Dispense	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness P05.09: Participant received less than 2 doses of IP during the study participation
US3812201	2020-11-02 (77)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
US3812215	2020-09-25 (38) 2020-12-23 (127)	Study Treatment Admin/Dispense Visit Scheduling Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812228	2020-08-29 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3812233	2020-09-17 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3812270	2021-01-01 (129)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3812275	2020-09-24 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3812287	2020-10-07 (41)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3812289	2020-08-28 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3812304	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3812309	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812332	2020-11-20 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812343	2020-09-23 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822006	2020-09-08 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3822008	2020-08-03 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-03 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-12-18 (137)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822027	2020-09-11 (37)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822027	2020-12-09 (126)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822038	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822047	2020-09-30 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822057	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822069	2020-09-11 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822071	2020-09-14 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822076	2020-09-02 (23)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-26 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822080	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822080	2020-09-15 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822081	2021-01-14 (157)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3822090	2021-01-19 (161)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3822091	2020-09-16 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822092	2020-12-28 (139)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822097	2021-01-13 (155)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822098	2020-09-16 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822098	2020-09-17 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822099	2020-09-17 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822104	2020-09-16 (36)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3822112	2020-12-22 (132)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822118	2020-09-16 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3822127	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3822132	2020-10-15 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822143	2020-08-14 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-19 (98)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3822148	2020-10-27 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822155	2020-09-21 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822156	2020-09-22 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822162	2020-09-23 (37)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822162	2020-11-13 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822173	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3822175	2020-09-09 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-09-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-19 (155)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822178	2020-09-23 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822182	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822187	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822190	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-21 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822191	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822200	2020-08-18 (-2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822207	2020-09-18 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3822214	2021-01-28 (162)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822229	2020-09-22 (33)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822236	2020-09-23 (31)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822239	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822240	2020-09-29 (37)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822243	2020-09-29 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822244	2020-12-17 (116)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822252	2020-09-28 (35)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822256	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822257	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822270	2020-09-17 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-09-28 (34)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-20 (148)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822272	2020-09-23 (29)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822273	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822273	2020-09-23 (29)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822283	2020-11-06 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822287	2021-01-12 (139)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822292	2020-09-30 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822295	2020-09-22 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-24 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3822299	2020-12-19 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822299	2020-12-23 (119)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822304	2021-01-02 (128)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-01 (186)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3822306	2020-09-23 (27)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822308	2020-09-23 (27)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822320	2020-12-18 (110)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822328	2020-09-03 (4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3822330	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822332	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3822334	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822357	2020-12-22 (111)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822365	2020-10-13 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-18 (107)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822372	2021-01-04 (123)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-02-04 (154)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3822378	2020-09-08 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822393	2020-10-05 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3822394	2020-10-22 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822402	2020-12-01 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-17 (92)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822406	2020-12-14 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822407	2020-12-18 (92)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-20 (94)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3822410	2020-10-19 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-11 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822411	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822417	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-04 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822418	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822421	2020-09-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822440	2020-09-25 (-24)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-19 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-08 (82)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3822446	2020-10-28 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3822448	2020-09-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822461	2020-11-17 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822467	2020-11-19 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832001	2020-07-30 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832002	2020-07-30 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832004	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832007	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832008	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832011	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2021-01-11 (165)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832012	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-21 (144)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832014	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832014	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3832016	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3832017	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832019	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832019	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832022	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832026	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832031	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832036	2020-08-31 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832037	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832039	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832042	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832049	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832052	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-21 (141)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832059	2020-08-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-15 (166)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-21 (172)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832061	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832068	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832074	2020-09-04 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3832076	2020-08-04 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3832107	2020-09-01 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832107	2020-11-05 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3832109	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-09 (216)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3832118	2020-09-25 (51)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832121	2020-10-28 (84)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832144	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3832151	2021-01-02 (145)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-02 (176)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832155	2020-12-21 (133)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832169	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832200	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832209	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832218	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832231	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832239	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832257	2021-02-03 (162)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-06 (165)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832272	2020-09-14 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2020-10-13 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3842005	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (23)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3842006	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3842007	2020-11-19 (81)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3842009	2020-11-19 (80)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3842012	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3842015	2020-10-02 (30)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3842029	2020-10-02 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3842038	2020-11-19 (66)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3842052	2020-09-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3842057	2020-12-27 (80)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3852001	2020-09-04 (16)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-13 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852004	2020-09-04 (15)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852005	2020-09-04 (15)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852009	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-26 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852011	2020-09-24 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852018	2020-10-21 (58)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3852019	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852031	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852033	2021-03-24 (211)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852035	2020-12-22 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852044	2020-09-27 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852045	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852049	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852050	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-28 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852051	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852054	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852057	2020-08-28 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
			P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-28 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852060	2021-03-22 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3852061	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3852063	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852064	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-13 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852070	2020-10-21 (52)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852079	2020-09-27 (27)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852095	2020-12-22 (111)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852100	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3852102	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852103	2020-09-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3852109	2021-03-24 (202)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852113	2020-09-04 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-03 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852116	2021-03-24 (202)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852124	2020-09-08 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-06 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-09 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-23 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3852130	2020-09-28 (21)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3852134	2020-09-08 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3852137	2020-12-01 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852142	2020-11-10 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852146	2020-09-09 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852146	2020-10-11 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852149	2020-12-29 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852166	2020-09-15 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3852167	2020-09-15 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3852172	2020-10-23 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-04 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852176	2020-09-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-24 (195)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852178	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852182	2020-10-20 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852185	2020-12-28 (104)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3852198	2020-12-26 (86)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862002	2021-01-29 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862011	2020-12-20 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862019	2020-08-24 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862020	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862020	2021-03-02 (198)	Concomitant Medication Missing Endpoint Assessments	P09.01: Prohibited concomitant medication or vaccine received by subject P07.01: Blood sample not taken when required per protocol
US3862022	2021-02-23 (191)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862044	2020-12-15 (117)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862048	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862053	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3862061	2020-08-24 (-1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862061	2021-01-13 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862067	2020-12-15 (112)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862070	2021-02-11 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862077	2020-08-27 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862095	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3862096	2020-09-14 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-01 (183)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862118	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3862124	2020-09-30 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3862130	2021-01-05 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862130	2021-02-04 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862139	2021-01-22 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862144	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862149	2020-12-15 (99)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862151	2020-10-06 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-15 (98)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862155	2020-12-16 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862166	2020-12-15 (97)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862171	2020-12-23 (104)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862177	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-15 (96)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862189	2020-10-14 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862196	2020-12-31 (107)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3862208	2020-09-16 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-31 (106)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862213	2020-10-20 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-15 (89)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862216	2020-09-18 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-16 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-13 (118)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-12 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-03 (167)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3862223	2020-10-01 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862227	2020-12-15 (79)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862230	2020-09-23 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-20 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3862241	2020-12-04 (72)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-11 (110)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862243	2020-12-02 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3862246	2020-09-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862252	2020-12-01 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3862256	2020-12-01 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3862263	2020-09-28 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862265	2020-11-04 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-08 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862267	2020-10-29 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862268	2021-01-04 (95)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862273	2020-09-30 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3862276	2020-10-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862279	2020-12-15 (75)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862281	2020-12-15 (64)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862290	2021-01-26 (98)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862293	2020-10-21 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-18 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872002	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872003	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872004	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3872005	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872008	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872012	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872015	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872027	2020-09-15 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872033	2020-09-15 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872053	2020-11-09 (97)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872068	2020-09-15 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872080	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872082	2020-08-06 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3872088	2020-09-04 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872091	2021-02-08 (186)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3872092	2021-02-27 (205)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3872095	2020-12-23 (139)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872100	2021-01-20 (167)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3872101	2020-09-05 (30)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-05 (121)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-10 (126)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3872109	2020-10-19 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872112	2020-12-24 (137)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-14 (158)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3872131	2021-03-03 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872143	2020-10-23 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872144	2020-10-23 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872145	2020-10-30 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872148	2020-12-03 (114)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-04 (115)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-06 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-07 (118)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-08 (119)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3872163	2020-09-17 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872173	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872187	2021-03-13 (212)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3872192	2020-10-23 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872201	2020-09-15 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-23 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872205	2021-01-13 (150)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3872215	2020-10-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872218	2020-10-26 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872220	2020-10-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872224	2020-11-05 (79)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872228	2020-09-16 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
	2020-10-02 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872234	2020-10-27 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872243	2020-10-07 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-04 (96)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-05 (97)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-07 (99)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-09 (101)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872243	2021-03-10 (192)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-03-12 (194)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3872247	2020-09-29 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-26 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872256	2020-10-05 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872259	2020-09-18 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-23 (95)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872260	2020-11-05 (74)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872260	2020-11-05 (74)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872271	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872273	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872277	2020-09-30 (38)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3872287	2020-10-02 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3872288	2020-10-02 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3872289	2020-09-30 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872292	2020-09-22 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872295	2020-10-05 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-21 (119)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-22 (120)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-23 (121)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-24 (122)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-25 (123)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-28 (126)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-29 (127)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-30 (128)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-31 (129)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-01 (130)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-02 (131)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872295	2021-01-03 (132)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-05 (134)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-06 (135)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3872300	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872315	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872317	2020-11-05 (72)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-11 (108)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-15 (112)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872317	2020-12-22 (119)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-24 (121)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-28 (125)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-01 (129)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3872320	2020-10-02 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-10 (196)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3872322	2020-09-24 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-03 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872324	2020-10-09 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872326	2020-10-16 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-26 (61)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872328	2020-10-02 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872329	2020-10-09 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-20 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872330	2020-10-15 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-20 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872331	2020-09-24 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872334	2020-10-08 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872337	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872340	2020-09-25 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872344	2020-10-09 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872356	2020-09-25 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872357	2020-10-06 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872359	2020-10-06 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-10 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872360	2020-10-06 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-10 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872361	2020-10-06 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872363	2020-11-23 (87)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872365	2020-10-15 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872367	2020-10-09 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-18 (82)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872369	2021-03-23 (207)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872373	2020-10-15 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872376	2020-08-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-26 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-07 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3872377	2020-12-03 (95)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-16 (108)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3872380	2021-02-28 (182)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3872381	2020-10-08 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-24 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872384	2020-10-14 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872384	2020-12-11 (103)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-26 (149)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3872385	2020-10-09 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-18 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872395	2020-09-28 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872398	2020-09-29 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872399	2020-10-15 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-20 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872401	2020-11-06 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872402	2020-11-04 (65)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872402	2020-11-20 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872403	2020-10-19 (49)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3872406	2020-09-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872407	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872408	2020-10-02 (32)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3872414	2020-10-01 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872418	2020-10-14 (43)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872418	2020-11-18 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872419	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872420	2020-10-19 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872422	2020-10-14 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872424	2020-10-14 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872428	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-13 (134)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3872430	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872433	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872434	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872435	2020-10-16 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872446	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-23 (82)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872447	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872449	2020-10-19 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872450	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872451	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-05 (94)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3872465	2020-11-18 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872472	2020-11-18 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872476	2020-09-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872482	2020-10-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-20 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872483	2020-10-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-20 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-23 (106)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872483	2021-01-20 (134)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3872484	2020-10-19 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872486	2020-10-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872488	2020-10-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-19 (72)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3872492	2020-10-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872495	2020-10-16 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872497	2020-11-18 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872507	2020-10-19 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-23 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872508	2020-10-19 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3882001	2020-08-26 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-27 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3882003	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-05 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3882003	2021-01-13 (136)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3882004	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-05 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3882006	2020-10-22 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3882018	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3882026	2021-02-03 (139)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3882027	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3882029	2020-11-03 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3882041	2020-10-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882042	2020-10-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882044	2021-01-06 (76)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3882047	2020-10-16 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882054	2020-10-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3882069	2020-10-23 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3892009	2020-10-01 (38)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3892024	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3892028	2020-08-28 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3892032	2020-11-16 (78)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3892059	2020-09-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3892069	2020-11-30 (82)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3892072	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3902001	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902005	2020-09-29 (29)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3902015	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-05 (59)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902015	2020-11-17 (71)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-17 (101)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3902017	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902019	2020-09-30 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-11-23 (83)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3902027	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902028	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902029	2020-09-03 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902034	2020-10-09 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3902054	2020-09-13 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3902055	2021-01-08 (122)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3902056	2020-09-25 (17)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3902057	2020-09-25 (17)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3902062	2021-03-23 (195)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902064	2020-10-15 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3902069	2020-10-16 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3902074	2020-10-09 (29)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3902079	2020-10-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902090	2020-10-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902100	2020-12-03 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3902101	2020-10-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902102	2020-10-29 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3902104	2020-10-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-11 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3902107	2020-10-21 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3902108	2020-12-03 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3902112	2020-09-24	Study Treatment Randomization	P04.02: Subject randomized in error
US3902115	2020-09-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-09 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902127	2020-11-15 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3902132	2020-12-06 (52)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3912007	2020-09-24 (30)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-09-30 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-03-09 (196)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3912025	2020-11-02 (67)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912028	2020-09-30 (34)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3912045	2021-01-14 (137)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912046	2020-10-26 (57)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912059	2021-01-20 (142)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3912074	2020-09-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3912075	2020-10-07 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3912087	2020-09-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3912099	2020-09-03 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3912105	2020-10-09 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912117	2020-12-19 (107)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3912125	2020-10-12 (35)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-11-09 (63)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-02-03 (149)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3912138	2020-11-13 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912139	2021-03-09 (182)	Data Privacy	I01.01: Breach of subject confidentiality
US3912140	2020-10-30 (52)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912149	2020-12-21 (102)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3912153	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912154	2021-03-26 (197)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912158	2020-11-03 (51)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912160	2020-11-20 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912161	2020-10-23 (39)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912163	2020-12-17 (94)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-23 (100)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3912167	2020-11-18 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912170	2021-01-23 (123)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912188	2021-02-02 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3912196	2020-11-03 (46)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912217	2020-10-26 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3912228	2021-02-28 (152)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3912229	2020-10-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3912233	2020-12-05 (59)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3922003	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922005	2020-08-26 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-27 (41)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3922006	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-01 (168)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3922008	2020-09-17 (30)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3922014	2020-09-18 (29)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3922041	2020-10-02 (37)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3922046	2020-10-30 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922046	2020-10-30 (64)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3922051	2020-12-15 (109)	Concomitant Medication Study Treatment Admin/Dispense	P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3922060	2020-11-24 (86)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-21 (144)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3922064	2020-08-31 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3922067	2020-09-14 (14)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3922085	2020-10-05 (28)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922086	2020-09-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3922089	2020-12-20 (104)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-12-22 (106)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-09 (124)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-11 (126)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3922099	2020-09-17 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922101	2020-11-13 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3922108	2021-02-24 (163)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3922118	2020-09-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3922131	2020-10-29 (38)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-31 (40)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-02 (42)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-04 (44)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-08 (48)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3922138	2020-11-13 (33)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922140	2020-11-13 (33)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
	2021-02-26 (138)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Inv Adequate Resources	I03.01: Untrained staff performing study procedures on subjects
US3922143	2020-11-13 (32)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3922149	2021-03-05 (143)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3922152	2020-11-13 (30)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3922160	2021-01-14 (88)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3922163	2020-12-07 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922163	2021-02-12 (116)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3922164	2021-01-09 (82)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-01-25 (98)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3922181	2021-01-08 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932001	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3932002	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-03 (71)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932003	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932003	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3932005	2020-09-21 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932025	2020-10-16 (49)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3932026	2020-09-26 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-17 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3932027	2020-08-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932032	2020-08-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932040	2020-08-31 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932046	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-05 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932048	2020-10-01 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932049	2020-12-25 (116)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3932051	2020-10-05 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-20 (81)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol P07.09: Time and date of each sample was not collected
US3932053	2021-03-22 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932065	2021-01-27 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3932082	2020-10-06 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932083	2021-02-26 (170)	Missing Endpoint Assessments Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3932087	2020-12-06 (90)	Missing Endpoint Assessments Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-08 (92)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-10 (94)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-09 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932088	2020-09-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932090	2020-10-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932093	2020-10-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932099	2020-10-17 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-05 (57)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab) P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3932100	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932100	2021-02-08 (152)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3932101	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3932104	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3932114	2021-03-04 (175)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3932120	2020-12-02 (82)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-05 (85)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932127	2021-02-22 (162)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3932136	2020-10-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-18 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932138	2020-11-18 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932143	2021-02-02 (140)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3932147	2020-09-16 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-07 (83)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-19 (95)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932148	2020-10-21 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3932153	2020-10-27 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932157	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932164	2020-12-02 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932171	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932176	2020-10-22 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932181	2020-11-20 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3932182	2020-09-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-01 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932184	2020-09-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932184	2020-12-01 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932195	2020-10-29 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932196	2020-11-02 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932204	2020-09-28 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-24 (58)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932205	2020-11-03 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932218	2020-10-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932228	2020-11-02 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932229	2020-11-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932230	2020-10-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-02 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2020-12-01 (56)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol P07.07: Saliva sample not collected when required per protocol
	2021-01-06 (92)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-12 (98)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932242	2020-11-17 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932243	2020-11-09 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932253	2021-02-17 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3932257	2020-11-18 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932261	2020-11-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932262	2020-10-15 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3932263	2020-11-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932273	2020-10-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3932277	2020-11-13 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932286	2020-10-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-03 (48)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-07 (52)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-18 (63)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3932289	2020-10-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932292	2021-02-09 (114)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
		Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932293	2020-11-15 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932295	2020-10-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942001	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942003	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-01 (12)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942005	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942006	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3942008	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3942010	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942010	2020-10-02 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3942038	2020-10-03 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942043	2020-12-23 (113)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3942044	2020-09-05 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-30 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-06 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3942071	2020-09-22 (19)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3942072	2020-09-11 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942080	2020-09-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942113	2020-10-07 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-11 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3942114	2020-09-26 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942115	2020-10-27 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942124	2020-09-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3942127	2020-09-27 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942129	2020-09-28 (7)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3942134	2020-10-29 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942142	2020-11-10 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-11 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3942144	2020-10-13 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942149	2020-11-12 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942151	2020-10-18 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942156	2020-10-15 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942160	2020-10-21 (8)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3952010	2021-03-24 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3952025	2021-01-22 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-12 (165)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3952033	2020-10-06 (35)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-07 (97)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3952040	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952040	2020-10-03 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952090	2020-10-16 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-05 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3952094	2020-12-31 (108)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-21 (129)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3952097	2021-02-04 (143)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3952102	2021-03-24 (189)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952134	2020-09-23 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3952141	2020-09-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-27 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952142	2020-12-02 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952154	2020-11-12 (49)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-23 (60)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3952156	2020-10-31 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952164	2020-12-04 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952169	2020-10-29 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-02 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952170	2020-09-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-27 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952173	2020-09-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3952177	2020-10-01 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-30 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952185	2020-09-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952185	2020-10-03 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3952188	2020-11-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952195	2020-11-02 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952199	2020-11-10 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952202	2021-03-23 (168)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3952208	2020-10-10 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3952217	2021-02-22 (137)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3962004	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3962010	2021-01-12 (146)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3962032	2021-02-01 (158)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3962033	2020-12-29 (123)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2020-12-31 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3962041	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3962056	2020-12-29 (119)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3962065	2020-09-16 (14)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-24 (113)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-28 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3962066	2021-02-18 (169)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3962067	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-29 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-05 (124)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3962096	2020-10-27 (49)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3962097	2021-01-13 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3972003	2020-09-30 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972004	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972022	2020-11-09 (77)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-12-14 (112)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3972028	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972031	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972039	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972041	2020-11-11 (77)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3972049	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972052	2020-10-24 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3972057	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972086	2020-09-01 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972089	2021-02-04 (156)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3972106	2020-09-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972107	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3972108	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972109	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972111	2020-09-22 (19)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972113	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972142	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972149	2020-10-16 (33)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-10-23 (40)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-10-29 (46)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3972150	2020-10-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972177	2020-10-16 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972192	2020-10-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-17 (182)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972200	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972214	2020-09-23 (-2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982004	2020-10-02 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982022	2021-01-05 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3982025	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-30 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3982027	2020-09-13 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982034	2020-09-11 (11)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-10 (40)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-09 (190)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3982051	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-11 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982068	2020-09-01 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982071	2020-10-29 (59)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982072	2020-10-06 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982075	2021-03-23 (204)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3982085	2020-09-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982092	2020-10-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982096	2020-10-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982122	2020-09-13 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3982124	2020-09-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982129	2021-01-27 (143)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-08 (155)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982146	2020-10-12 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982151	2020-10-05 (26)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982175	2020-09-26 (12)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982184	2020-10-14 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982195	2020-09-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3982196	2020-10-30 (44)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-15 (90)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2020-12-16 (91)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982199	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-20 (156)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
	2021-03-24 (188)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3982205	2020-10-15 (28)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-11-20 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982210	2020-10-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982212	2020-09-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982215	2021-01-28 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982226	2020-10-21 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3982238	2020-09-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3982245	2020-09-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-02 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (11)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982248	2020-12-04 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982256	2020-11-26 (58)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3982257	2020-11-01 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982258	2020-10-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992002	2020-11-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992010	2020-11-17 (60)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3992019	2020-11-03 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3992026	2020-11-02 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-15 (114)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992027	2020-12-04 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992030	2020-12-11 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992032	2020-09-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-17 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992037	2020-10-30 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-06 (103)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992038	2020-09-26 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-23 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992039	2020-09-26 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-03 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992039	2020-12-28 (94)	Missing Endpoint Assessments Visit Scheduling	P07.01: Blood sample not taken when required per protocol P10.01: Onsite Visits not performed or out of window
US3992040	2020-10-23 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-07 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-26 (123)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3992044	2020-09-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3992046	2020-10-23 (25)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992053	2020-12-02 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992054	2020-10-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992054	2020-12-09 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992057	2020-10-23 (22)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-14 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992066	2020-11-18 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992076	2020-12-02 (56)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3992078	2020-10-09 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3992082	2020-10-23 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992089	2020-10-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: Placebo

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992094	2020-10-12 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3992103	2020-11-18 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992105	2020-10-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3992114	2020-10-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3992119	2020-11-30 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-12 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-22 (94)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992120	2020-12-17 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3992123	2020-11-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002003	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002005	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002007	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002010	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002017	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002023	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002024	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002042	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002062	2020-08-27 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002067	2020-08-28 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002080	2021-03-17 (227)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002111	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3002135	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-06 (153)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3002137	2020-10-28 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002146	2020-11-19 (101)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-24 (106)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002158	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002161	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002172	2020-12-08 (111)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3002206	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3002221	2020-09-30 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002234	2020-10-01 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002246	2020-10-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (107)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002250	2020-10-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002250	2020-10-03 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002252	2020-10-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002263	2020-10-06 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3002285	2020-10-29 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002311	2020-10-19 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002316	2020-10-18 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3002320	2020-10-23 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002327	2020-11-03 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3002337	2020-12-08 (70)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3002344	2020-10-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-07 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3002354	2020-11-06 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3002357	2020-12-07 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3002358	2020-10-14 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3012001	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012004	2020-08-03 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012007	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012009	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-24 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012010	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012011	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012012	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012013	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012016	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-26 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-02 (37)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3012019	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012021	2020-08-26 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012023	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-11 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012023	2020-08-25 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012026	2020-08-26 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012030	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012034	2020-08-27 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012035	2020-08-27 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3012036	2020-08-27 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012038	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012039	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012042	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3012045	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012046	2020-01-06 (-207)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012048	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012049	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-28 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012053	2020-08-13 (8)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012054	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012056	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012058	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012059	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012064	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012068	2020-08-06 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012068	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012069	2020-09-09 (35)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012070	2020-09-03 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012075	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012083	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012084	2020-09-04 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012086	2020-09-09 (34)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3012087	2020-09-14 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3012103	2020-09-29 (50)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012107	2020-09-02 (23)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3012150	2020-09-14 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3012161	2020-09-02 (17)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3012185	2020-12-18 (122)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3012186	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3012226	2020-08-29 (5)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3012240	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3012242	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3012246	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-01 (32)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3012281	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3012293	2020-10-26 (46)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3012310	2020-09-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3012317	2020-09-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-21 (38)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-02-26 (166)	Study Procedures/Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3022006	2020-09-08 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022006	2020-09-08 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022009	2020-09-04 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022012	2020-07-27 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-23 (89)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022013	2020-11-05 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022019	2020-08-01 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3022031	2020-09-02 (38)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3022040	2021-02-22 (210)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022043	2020-07-27 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-24 (59)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-29 (64)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022052	2020-09-11 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022055	2020-08-01 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-01 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022062	2020-07-28 (-1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-17 (81)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3022069	2020-09-11 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022074	2020-09-10 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022075	2020-09-10 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-05 (161)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
		Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2021-01-13 (169)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3022081	2020-09-15 (49)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022086	2020-08-07 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3022091	2020-09-15 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022092	2020-09-11 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-05 (98)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022103	2020-11-23 (116)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022122	2020-12-16 (134)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3022125	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-05 (92)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022126	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3022130	2020-11-05 (91)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3022140	2020-11-30 (112)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022150	2020-08-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022154	2020-10-21 (66)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-30 (106)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022173	2020-10-07 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022194	2020-11-13 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022202	2020-10-05 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3022208	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-03 (106)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022238	2021-01-18 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3022269	2020-11-30 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022302	2020-09-05 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3022305	2020-11-30 (89)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3022316	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3022321	2020-09-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3022324	2021-03-19 (163)	Inv Safety Rptg (Reg/Sponsor) Study Procedures/Assessments	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3022336	2020-10-09 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032001	2020-08-02 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3032007	2020-09-08 (44)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3032016	2020-09-01 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032042	2020-10-19 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-04 (219)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032054	2021-01-22 (177)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3032063	2020-09-02 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032072	2020-09-09 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032072	2020-09-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032082	2020-09-29 (57)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032088	2021-01-07 (157)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3032092	2020-08-08 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3032093	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032106	2020-09-09 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032115	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-09 (126)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032115	2021-01-04 (152)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3032122	2020-09-04 (30)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3032126	2020-11-05 (92)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3032138	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3032148	2020-09-11 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3032149	2020-09-15 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032162	2020-09-10 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032183	2020-09-11 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032184	2020-09-23 (44)	Study Treatment Admin/Dispense	P05.11: More than 8 hours between completion of dosing syringe fill and dose administration.
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032196	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3032223	2020-10-29 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032238	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3032247	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032294	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032297	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032312	2021-03-23 (215)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3032313	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (42)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3032334	2020-09-25 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3032346	2020-09-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-30 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3032347	2020-09-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-30 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3032354	2020-10-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3042004	2020-07-27 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042010	2020-07-27 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042014	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042017	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-02 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-06 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042021	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042022	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042027	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042029	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042031	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042034	2020-07-29 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042038	2020-07-29 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042039	2020-08-30 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042040	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042050	2020-09-04 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042066	2020-09-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042075	2020-09-13 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042077	2020-09-09 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042084	2020-08-05	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3042112	2020-09-08 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042119	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042139	2020-09-17 (38)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3042149	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042154	2020-09-07 (27) 2020-10-23 (73)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3042157	2020-09-14 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042166	2020-08-15 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3042192	2020-09-11 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042192	2020-09-11 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3042211	2020-12-29 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3042217	2020-07-27 (-21)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3042219	2021-01-07 (144)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3042223	2020-09-22 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3042229	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3042233	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-02 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3042233	2020-10-02 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3042247	2020-09-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042269	2020-08-21 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3042285	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3042299	2020-10-05 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3042321	2020-10-07 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052003	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052005	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052007	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052008	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052010	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-08-25 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-16 (171)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3052013	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052013	2020-08-27 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052014	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052015	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052018	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052021	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (27)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052025	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052026	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052027	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-01 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052028	2020-07-30 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-08-25 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3052032	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052034	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052035	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052035	2020-09-30 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052036	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052039	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052041	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052043	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052046	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052050	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052056	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052057	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052058	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052059	2020-07-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052061	2020-07-31 (1)	ICF Process/Timing Study Treatment Randomization	I02.04: Informed consent not signed and/or dated by appropriate site staff P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052063	2020-07-31 (1)	ICF Process/Timing Study Treatment Randomization	I02.04: Informed consent not signed and/or dated by appropriate site staff P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-15 (138)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052066	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052067	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052070	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-03 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052074	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052077	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-03 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3052078	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-09 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3052082	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052086	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052087	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052089	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052093	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-08 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052094	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-03 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052095	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-08 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052096	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-08 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052100	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052102	2020-08-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-27 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052104	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052106	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052107	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052108	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052110	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052111	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052111	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3052114	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052118	2020-08-06 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052120	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052124	2020-08-07 (1)	ICF Process/Timing Study Treatment Randomization	I02.04: Informed consent not signed and/or dated by appropriate site staff P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052127	2020-08-07 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.04: Informed consent not signed and/or dated by appropriate site staff P07.10: Subject Diary not completed 30 min post dosing
US3052128	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052129	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052130	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052131	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-03-10 (216)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052132	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (36)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-12 (218)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052135	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052137	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-10 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052140	2020-08-07 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052140	2020-09-10 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-21 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052142	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052145	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052148	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052150	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052153	2020-08-07 (-3)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052158	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-16 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052159	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-23 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052161	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-17 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-10 (212)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052162	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052164	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052166	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052166	2020-09-16 (37)	Missing Endpoint Assessments Visit Scheduling	P07.06: Nasopharyngeal swab sample not collected when required per protocol P10.01: Onsite Visits not performed or out of window
US3052167	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052169	2020-08-11 (-1) 2020-09-18 (38)	ICF Process/Timing Study Treatment Admin/Dispense Visit Scheduling	I02.04: Informed consent not signed and/or dated by appropriate site staff P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3052171	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052173	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052175	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052178	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052181	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052182	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052184	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-09-16 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052185	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052186	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052190	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052191	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052193	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052196	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-11 (152)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3052198	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052199	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052201	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052207	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052208	2020-08-13 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052210	2020-08-13 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052212	2020-08-13 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052216	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-11 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052218	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052219	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-29 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052224	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052225	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052225	2021-02-25 (196)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052228	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052229	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052238	2020-10-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052242	2020-10-26 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052243	2020-09-16 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.06: Nasopharyngeal swab sample not collected when required per protocol P07.10: Subject Diary not completed 30 min post dosing
US3052250	2020-09-24 (38)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052260	2020-09-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052262	2020-09-24 (38)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3052266	2020-08-14 (-5)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052267	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052268	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3052269	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052271	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3052279	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052289	2021-02-20 (184)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052292	2020-09-25 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052293	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-22 (214)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052297	2021-03-05 (194)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052298	2020-09-24 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052301	2020-10-27 (65)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052304	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052309	2021-03-12 (197)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052318	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052319	2021-01-25 (151)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052321	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052322	2020-09-21 (25)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052324	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052327	2020-08-28 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-28 (32)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-21 (147)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052328	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-10 (102)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3052336	2020-10-07 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052337	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3052339	2020-09-29 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3052341	2020-11-10 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052348	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3052350	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3052355	2020-09-02 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-05 (4)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3052356	2020-10-02 (31)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3052359	2020-12-17 (106)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3052378	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3062004	2020-07-30 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062017	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-01 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3062033	2020-10-15 (76)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3062039	2020-08-09 (7)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3062054	2021-02-10 (192)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-12 (194)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-14 (196)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062064	2020-08-08 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3062078	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062081	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3062103	2020-09-10 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3062120	2020-09-09 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3062139	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3062176	2020-08-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3062196	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3062208	2020-08-15 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3062215	2020-10-20 (71)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062215	2021-03-05 (207)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3062227	2020-09-11 (29)	Inv Qualifications/Agreements	I06.01: Investigator or site staff not qualified to perform trial procedures
US3062263	2021-02-26 (196)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-28 (198)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3062265	2020-08-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-25 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-21 (68)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3062276	2020-09-18 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3062277	2021-03-07 (203)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3062303	2020-10-16 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3062304	2020-11-13 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3062306	2020-09-13 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-11 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3062317	2020-10-03 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3082005	2020-08-06 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-28 (144)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082005	2020-12-28 (144)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-18 (224)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3082007	2020-09-24 (49)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3082010	2020-08-09 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-08 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-24 (46)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3082023	2021-01-06 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3082051	2020-09-24 (38)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3082059	2020-09-24 (37)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3082078	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082078	2021-01-07 (140)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3082081	2020-09-24 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3082087	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3082096	2020-12-30 (129)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3082103	2021-01-28 (157)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3082119	2020-08-25 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3082129	2020-10-12 (47)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082181	2020-09-17 (16)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082181	2020-10-03 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-19 (140)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3082191	2020-10-15 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3082199	2020-10-12 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082200	2020-09-24 (21)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3082218	2020-10-12 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3082219	2020-11-18 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3082231	2021-01-05 (117)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3082258	2020-09-16 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3092002	2020-11-16 (105)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092004	2020-10-09 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092005	2020-10-16 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092007	2020-08-06 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3092010	2020-10-12 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092011	2020-09-12 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092014	2020-09-14 (42)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092014	2020-09-14 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092017	2020-09-14 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-19 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092020	2020-09-14 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092022	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092023	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-14 (41)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092023	2020-11-19 (107)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-16 (224)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092027	2020-10-15 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-26 (206)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3092031	2020-10-20 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092032	2020-10-07 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-15 (222)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092035	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-12 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092036	2020-09-03 (29)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
US3092039	2020-09-11 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092042	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092044	2020-10-14 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092052	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-06 (61)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092053	2020-08-11 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3092056	2020-09-14 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-29 (145)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092057	2021-02-26 (204)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3092061	2020-09-09 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-10 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092063	2020-09-18 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092064	2020-09-21 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092069	2020-08-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3092073	2020-09-08 (32)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-09 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-29 (175)	ICF Process/Timing	I02.01: Signed informed consent not available on site

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092074	2020-10-26 (80)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3092079	2020-10-01 (55)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092082	2020-10-06 (60)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-10 (64)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092083	2020-09-14 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092084	2020-09-14 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092091	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092096	2020-10-01 (53)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-02-24 (199)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092097	2020-08-15 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092107	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-13 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-06 (57)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092108	2020-08-15 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-21 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092111	2020-09-08 (29)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092112	2020-08-15 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-28 (49)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-29 (50)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3092124	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092127	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-13 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092140	2020-10-22 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092151	2021-01-05 (140)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092170	2020-08-25 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3092172	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092173	2020-09-21 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092174	2020-11-10 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092175	2020-08-19 (-1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-24 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3092181	2020-10-06 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092184	2021-03-03 (195)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092186	2020-10-08 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092194	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092195	2020-08-29 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-26 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3092196	2020-10-03 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092197	2020-08-26 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-09 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092199	2020-09-29 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092206	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-02 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092207	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092208	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092216	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092217	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-31 (7)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-07 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092218	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092219	2020-08-25 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-08 (45)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3092221	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092224	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092227	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092230	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3092234	2020-10-30 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3092239	2020-10-13 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3092249	2020-10-02 (37)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3092260	2020-10-05 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092273	2021-01-06 (131)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3092276	2020-09-02 (1) 2020-10-02 (31)	Study Procedures/Assessments Study Treatment Admin/Dispense	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects) P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3092300	2021-03-15 (193)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3102002	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102004	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102005	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102008	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102015	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-19 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102016	2020-07-28 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3102020	2020-11-05 (101)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102023	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102024	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102028	2020-09-11 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3102035	2021-01-15 (171)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-02-20 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102038	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102049	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102054	2021-01-27 (183)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102055	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102057	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102066	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102067	2021-03-13 (227)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102068	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102072	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102085	2020-12-06 (126)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102089	2021-01-11 (162)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102102	2021-02-02 (183)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102109	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3102111	2020-10-12 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3102122	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3102123	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3102132	2021-03-01 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102137	2020-09-03 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3102141	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-09 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102141	2021-03-06 (212)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102152	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-28 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102160	2020-12-28 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102163	2020-09-11 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102169	2020-11-15 (97)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102174	2020-10-08 (59)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-11 (62)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-30 (173)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102179	2020-08-29 (19)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-03-06 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102211	2020-09-18 (32)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2020-10-13 (57)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3102217	2021-03-12 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102219	2021-03-12 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102229	2020-10-09 (52)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3102230	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-18 (122)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102232	2020-09-21 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102239	2020-09-16 (28)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3102240	2021-03-14 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102246	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102249	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-11 (203)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102260	2021-03-08 (197)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102262	2020-10-11 (48)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102262	2020-12-08 (106)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3102268	2021-03-19 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102281	2021-01-06 (133)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
	2021-02-13 (171)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102282	2021-02-21 (179)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102289	2021-01-22 (148)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102293	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3102313	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102313	2020-10-07 (37)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3102318	2020-10-01 (29)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3102321	2020-09-30 (27)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-03-08 (186)	Concomitant Medication Study Treatment Admin/Dispense	P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3102322	2020-11-16 (74)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3102328	2020-09-25 (17)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102333	2020-09-25 (16)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102339	2020-09-25 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102346	2020-09-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3102351	2020-09-25 (14)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102355	2020-10-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3102362	2020-10-16 (32)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3102371	2020-09-14 (-3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102378	2020-12-09 (83)	Missing Endpoint Assessments	P07.09: Time and date of each sample was not collected
US3102383	2020-12-31 (105)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3102402	2020-09-13 (-16)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3102405	2020-11-09 (40)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3102406	2020-10-04 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-16 (47)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3102414	2020-11-02 (27)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3102415	2020-10-04 (-4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-05 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112016	2020-09-01 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112032	2020-07-30 (1)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
	2020-08-27 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-28 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112033	2021-03-22 (236)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112050	2020-08-28 (29)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
US3112061	2020-12-01 (121)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112065	2020-09-05 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112078	2020-08-31 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-31 (150)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3112083	2021-03-09 (218)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3112089	2020-09-01 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3112097	2020-08-04 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2020-09-03 (31)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3112101	2021-01-29 (178)	Withdrawal/Term Criteria	P11.01: Anytime withdrawal criteria are met but subject was not withdrawn
US3112116	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112128	2020-09-24 (50)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-02-22 (201)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3112146	2020-09-08 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112148	2020-09-11 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-19 (166)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3112152	2020-08-11 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-05 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112191	2020-09-09 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112197	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112199	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112215	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3112256	2021-03-12 (211)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3112257	2020-08-14 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-12 (30)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-14 (154)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3112271	2020-09-18 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112272	2020-08-17 (-8)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3112277	2020-08-17 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112282	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112285	2020-08-22 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112286	2020-09-20 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112294	2020-08-26 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3112296	2020-10-01 (45)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112302	2020-09-20 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112313	2021-01-05 (141)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112329	2020-09-18 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112338	2020-09-18 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112343	2020-09-21 (32)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3112350	2020-09-21 (32)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3112354	2020-09-24 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3112385	2020-08-31 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112397	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3112407	2020-10-03 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3112437	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3112457	2020-09-09 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3112463	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3112466	2020-09-01 (-9)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3122001	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122002	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-02 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122005	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122007	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122010	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3122014	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (82)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122017	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122019	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122020	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-25 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-26 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122021	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-25 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122022	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122024	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (82)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-18 (207)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
	2021-02-20 (209)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3122027	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122028	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122029	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122034	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122034	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122038	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-09 (198)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3122041	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122044	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122045	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122046	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122047	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-21 (179)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3122051	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122054	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122054	2020-07-29 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122056	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122057	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3122060	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122062	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122064	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122065	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-08 (196)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122066	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122071	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122072	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-29 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3122073	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122075	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122077	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122079	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122080	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122082	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122086	2020-07-27 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122087	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-29 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122087	2020-08-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3122089	2020-07-29 (2)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122094	2020-10-13 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3122097	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-30 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-06 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3122098	2020-08-25 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122100	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122104	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-27 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-28 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3122108	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-30 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-25 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-27 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122111	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-07 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122113	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122115	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-07-30 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-25 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122124	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-06 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3122128	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3122130	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-10 (135)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3122133	2020-10-05 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3122134	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3122145	2020-09-30 (30)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3122146	2020-09-24 (24)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3132007	2020-08-07 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-09-15 (40)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3132011	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3132021	2020-08-18 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3132031	2020-08-27 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132032	2020-10-29 (63)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3132037	2020-09-02 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3132060	2020-09-16 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3132093	2020-09-30 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-28 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3132101	2020-11-13 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3132102	2020-10-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132105	2020-11-14 (41)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol P07.09: Time and date of each sample was not collected
	2020-12-14 (71)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3132108	2020-11-05 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3132109	2020-11-05 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3132112	2021-01-18 (102)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3132118	2020-10-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-17 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132118	2020-11-17 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3132119	2020-11-06 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3132131	2020-10-16 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3132136	2020-11-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3132137	2020-11-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-21 (95)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3132146	2020-11-17 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3132149	2020-11-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3132149	2021-01-05 (77)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-15 (87)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-01-16 (88)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3132163	2020-11-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3142001	2020-09-24 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3142008	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-19 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142009	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-04 (37)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142009	2020-11-23 (117)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142010	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (28)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-08-31 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-01 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142012	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-22 (177)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142016	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-28 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142017	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-01 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142017	2020-09-04 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-23 (117)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142018	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-12 (167)	ICF Process/Timing	P07.10: Subject Diary not completed 30 min post dosing I02.02: Wrong informed consent version signed
US3142019	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-25 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3142021	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-01 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-14 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142022	2020-07-30 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-25 (239)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3142026	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142028	2020-08-26 (27)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-12 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142029	2020-08-26 (27)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-13 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142030	2020-09-02 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-28 (182)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142031	2020-09-02 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142035	2020-08-26 (27)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142038	2020-09-16 (48)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3142039	2020-08-27 (28)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-27 (181)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142041	2020-08-27 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-18 (202)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142042	2021-01-29 (182)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142048	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-02 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142051	2020-09-01 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-10 (194)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142058	2020-09-01 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142060	2020-09-01 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142063	2020-09-01 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-05 (187)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142064	2020-09-03 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142065	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-18 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142068	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-22 (204)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142071	2020-09-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142074	2021-01-22 (173)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142075	2020-09-08 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142076	2020-07-30 (-4)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-11 (162)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142080	2021-01-08 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142081	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142082	2020-09-01 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-21 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142084	2020-09-03 (31)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3142087	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142091	2020-09-02 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3142095	2020-09-08 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142098	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-01 (182)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142099	2020-09-08 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-22 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142101	2020-08-18 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142103	2020-09-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142110	2020-07-31 (-5)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-04 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-08 (157)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142112	2020-09-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142113	2020-09-08 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142114	2020-09-03 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142117	2020-09-09 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142121	2020-09-08 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-22 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-13 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142124	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142125	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142129	2020-09-02 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3142130	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142131	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-28 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142132	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142134	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-16 (133)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3142138	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142141	2020-08-20 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3142146	2021-01-22 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142149	2021-01-22 (169)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142153	2020-09-02 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142156	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-20 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142157	2020-09-03 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3142160	2020-09-03 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142163	2021-01-29 (175)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142164	2020-09-04 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142165	2020-09-04 (28)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
	2020-11-04 (89)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3142166	2021-01-15 (144)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142167	2021-01-28 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142173	2020-08-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-02 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-09 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142175	2020-09-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142176	2020-09-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-17 (39)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142178	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142185	2020-09-19 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-12 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142186	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142187	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142189	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3142203	2020-09-24 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-27 (47)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142208	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142210	2020-09-21 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-15 (125)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-20 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142211	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142213	2021-01-28 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142220	2020-09-10 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-29 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142224	2020-10-05 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-11 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142227	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142229	2020-08-19 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3142230	2020-09-24 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-01 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142235	2021-01-08 (144)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3142237	2020-10-28 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-15 (119)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3142239	2021-01-18 (153)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol
US3142242	2021-01-20 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142243	2020-11-04 (78)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142245	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-01 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142251	2020-09-24 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3142254	2020-11-27 (94)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-22 (150)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142257	2021-02-05 (142)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142258	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-28 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-26 (154)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3142261	2021-01-19 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3142263	2021-03-21 (203)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3142265	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3142268	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-17 (105)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-15 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142270	2021-01-14 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3142272	2021-01-08 (120)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152002	2020-07-27	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3152004	2020-12-21 (148)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152004	2020-12-21 (148)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152007	2020-07-28 (2)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-07-29 (3)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152009	2020-08-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152018	2021-01-07 (164)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152023	2020-07-30 (2)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152026	2020-09-01 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3152052	2020-10-04 (67)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-02 (126)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-06 (130)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152066	2020-10-19 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152071	2021-02-09 (191)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-16 (198)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3152089	2020-09-11 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152100	2020-08-08 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152102	2020-08-06 (1)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152113	2020-08-14 (8)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152121	2020-08-16 (7)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152121	2020-09-14 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window
	2020-10-06 (58)	Visit Scheduling	
US3152129	2020-08-23 (14)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-22 (166)	ICF Process/Timing	
US3152130	2020-09-15 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-05 (208)	Study Procedures/Assessments	
US3152157	2020-09-15 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152160	2021-02-11 (183)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152176	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152176	2021-02-28 (200)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3152201	2020-11-12 (91)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3152204	2020-08-19 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152214	2020-10-28 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152218	2020-09-23 (41)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152236	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152254	2020-08-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3152274	2021-03-13 (211)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152281	2020-09-29 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-13 (58)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152321	2020-09-21 (33)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152322	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152327	2020-09-22 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3152339	2020-08-29 (9)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152350	2020-08-28 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152361	2020-12-16 (118)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152361	2020-12-16 (118)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3152375	2020-09-25 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152377	2020-09-03 (14)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-26 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-16 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-18 (120)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152396	2020-09-14 (12)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3152406	2020-09-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152420	2020-11-10 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152428	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152439	2020-10-07 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152440	2020-10-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3152459	2020-12-07 (61)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-09 (63)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3152480	2020-11-20 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152485	2020-11-18 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152492	2020-11-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152496	2020-11-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3152497	2020-11-19 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152502	2020-10-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152519	2020-10-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3152525	2020-11-25 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3152545	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3152547	2021-03-03 (132)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3162002	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162003	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3162007	2020-07-28 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3162011	2021-02-20 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162017	2020-08-04 (7)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162021	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162025	2020-09-08 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162026	2021-02-21 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162031	2020-07-30 (1)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162031	2020-08-04 (6)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-28 (91)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3162040	2020-08-04 (5)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-02 (156)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-23 (208)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3162042	2020-07-30 (-26)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3162048	2021-02-19 (201)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3162050	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-28 (147)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162053	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162055	2020-09-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162062	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162066	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-06 (154)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3162070	2020-09-08 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162074	2020-09-08 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3162078	2020-09-08 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3162080	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162081	2021-02-12 (190)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3162084	2020-09-13 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-14 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3162106	2020-09-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162114	2020-10-07 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162143	2020-09-08 (22)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-12 (117)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-24 (219)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162153	2020-09-08 (21)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3162154	2020-09-18 (30)	Accidental Unblinding	P12.01: Inadvertent unblinding of site personnel
US3162157	2020-10-02 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3162175	2021-03-24 (216)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3162177	2021-03-24 (216)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162179	2020-09-08 (16)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3162190	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3162202	2020-08-28 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3162218	2020-10-29 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162221	2020-10-29 (56)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-07 (126)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3162241	2020-09-16	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3162245	2020-09-08 (-8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3162267	2020-10-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3162278	2020-11-13 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172003	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172005	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172008	2020-09-24 (49)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172031	2020-09-15 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172032	2020-08-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-02 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172034	2020-08-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172039	2020-09-15 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172040	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172048	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3172050	2020-10-14 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172057	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172061	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172062	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172065	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-16 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172072	2020-09-10 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172073	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172076	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172076	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172082	2020-08-20 (8) 2021-01-13 (154)	Study Treatment Randomization Study Treatment Admin/Dispense	P04.03: Subject enrolled/dosed at two sites P05.13: Subject received more than 2 doses of mRNA-1273
US3172110	2020-10-22 (70)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3172111	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-16 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172112	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172115	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172121	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172125	2020-08-13	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3172129	2020-09-11 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-24 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3172135	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172153	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3172157	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172161	2020-11-02 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172167	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172172	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-16 (59)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172173	2020-08-19 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3172174	2020-09-22 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172175	2020-10-27 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172183	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172187	2020-10-28 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172195	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-17 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172207	2020-10-27 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172209	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172212	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172214	2020-08-18	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3172216	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172217	2020-09-23 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172219	2020-10-28 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172235	2020-08-19	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3172242	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172243	2020-10-23 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172246	2020-09-29 (41)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172257	2020-10-26 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172259	2020-10-27 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172265	2020-09-18 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172267	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172268	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (70)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-29 (162)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172269	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172275	2020-10-26 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172281	2020-10-27 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172297	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-27 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172301	2020-10-29 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172307	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172310	2021-02-23 (183)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172312	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172313	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-24 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3172314	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172315	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172317	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172318	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172318	2020-09-22 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3172321	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172323	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172326	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-29 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172327	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172328	2020-10-27 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172330	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172345	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3172355	2020-09-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172359	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172362	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172365	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172382	2020-10-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172383	2020-10-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3172387	2020-10-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-15 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172391	2020-10-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172394	2020-11-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172398	2020-11-18 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172432	2020-10-20 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3172441	2020-10-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172459	2020-11-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172466	2020-12-16 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172469	2020-11-18 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172473	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-18 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3172474	2020-11-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172477	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-26 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3172479	2020-11-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172481	2020-11-26 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172481	2020-11-26 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3172483	2020-11-26 (36)	Study Treatment Admin/Dispense Visit Scheduling	P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3172488	2020-10-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-19 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3172492	2020-11-19 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-22 (123)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3172499	2020-11-27 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3172499	2020-11-27 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182001	2020-07-27 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182002	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182005	2020-07-27 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182008	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182009	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182014	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182014	2021-02-17 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
			P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3182015	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182018	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182019	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-21 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182020	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182024	2020-08-26 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182025	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182027	2020-07-28 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182031	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182033	2020-09-01 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182035	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182037	2020-07-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182037	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182038	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182041	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182042	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182046	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-01 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182048	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182053	2020-07-30 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182056	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182057	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182058	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-07-31 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-24 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182064	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182066	2020-08-11 (14)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182069	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182073	2020-09-03 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182082	2020-08-06 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-27 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182084	2020-09-03 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182087	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182089	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-28 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3182091	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182100	2020-08-31 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182102	2020-08-27 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182108	2020-08-03 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
			P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3182117	2020-09-04 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182119	2020-09-09 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3182122	2020-09-01 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182133	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182157	2020-08-31 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182159	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182165	2020-09-03 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182180	2020-09-11 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3182194	2020-08-15 (10)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3182197	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182209	2020-08-19 (14)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3182221	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182240	2020-08-10 (-3)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3182244	2020-08-14 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (131)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3182248	2020-10-23 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3182264	2020-09-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182269	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3182278	2020-08-19 (9)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3182283	2020-12-10 (122)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3182319	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3182360	2020-09-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3182361	2020-09-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192001	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192004	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192004	2020-08-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-05 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192006	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192010	2020-08-01 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-29 (29)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3192012	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192013	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192017	2020-08-01 (-1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192018	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-10-17 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192020	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192023	2020-08-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192026	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192027	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192027	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192029	2020-08-03 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192035	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192036	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192037	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192038	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192038	2020-09-06 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-14 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192040	2020-08-03 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192042	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192045	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192046	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192048	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192051	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-10 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192052	2020-08-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192055	2020-08-04 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192056	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192056	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-23 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192063	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-02-16 (196)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192065	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192066	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-04 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192067	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192068	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-15 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192074	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-08-31 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192076	2020-08-05 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-02 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192077	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192079	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192080	2020-08-06 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192082	2020-08-06 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192083	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-02 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192086	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3192099	2020-08-07 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192102	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192112	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192114	2020-09-05 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-23 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192116	2020-08-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192119	2020-09-05 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192149	2020-09-06 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3192168	2021-03-06 (209)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
	2021-03-07 (210)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3192173	2020-12-23 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192174	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-11 (33)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192176	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192181	2020-08-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192183	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192189	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192203	2021-01-16 (158)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192208	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192211	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192212	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192218	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192219	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192222	2020-08-13 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192223	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192224	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192226	2020-08-13 (1) 2020-10-23 (72)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3192230	2020-08-13 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192232	2020-08-13 (1)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192233	2020-08-13 (1) 2020-09-18 (37)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3192236	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192239	2020-08-14 (1) 2020-09-11 (29) 2020-11-18 (97)	ICF Process/Timing Missing Endpoint Assessments Visit Scheduling	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192240	2020-08-14 (1) 2020-09-11 (29)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192241	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192243	2020-08-14 (1) 2020-12-18 (127)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192245	2020-08-14 (1) 2020-09-11 (29)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192248	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192251	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192252	2020-08-14 (1) 2020-10-05 (53)	ICF Process/Timing Study Treatment Admin/Dispense Visit Scheduling	I02.02: Wrong informed consent version signed P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3192253	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192253	2020-10-05 (53)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3192254	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192255	2020-08-14 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192259	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192260	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192262	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192264	2020-08-15 (1) 2020-09-11 (28)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3192270	2020-08-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.10: Subject Diary not completed 30 min post dosing
US3192277	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192278	2020-08-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192279	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192280	2020-08-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192282	2020-08-15 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192283	2020-08-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192287	2020-08-15 (1) 2020-10-19 (66)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3192288	2020-08-15 (1)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192289	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192292	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192295	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192296	2020-08-16 (1) 2021-01-21 (159)	ICF Process/Timing Study Treatment Admin/Dispense	I02.02: Wrong informed consent version signed P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192297	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192298	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192299	2020-08-16 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192300	2020-08-16 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192300	2020-09-21 (33)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192302	2020-08-16 (-7) 2020-09-26 (35)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192303	2020-08-16 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192304	2020-08-16 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192305	2020-08-16 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192310	2020-08-16 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192311	2020-08-16 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192315	2020-08-17 (-7) 2020-08-24 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192320	2020-08-17 (-9)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-12-05 (102)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-06 (103)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-08 (105)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-10 (107)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3192322	2020-08-17 (-8)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192323	2020-08-17 (-14)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192327	2020-08-17 (-5)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192329	2020-08-17 (-6)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-08-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192330	2020-08-18 (-16)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192334	2020-08-18 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192342	2020-08-18 (-15) 2020-11-09 (69)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3192345	2020-08-19 (-4)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192348	2020-08-19 (-3) 2020-08-22 (1)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192349	2020-08-19 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192350	2020-08-19 (-6)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192352	2020-08-19 (-5) 2021-02-15 (176)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3192353	2020-08-19 (-14) 2020-09-02 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192355	2020-08-19 (-5) 2020-08-24 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192356	2020-08-19 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192357	2020-08-19 (-8)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-16 (174)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-17 (175)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-18 (176)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192358	2020-08-19 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192359	2020-08-19 (-8)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192360	2020-08-19 (-3)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192362	2020-08-25 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192363	2020-08-19 (-7)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3192369	2020-08-20 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192382	2020-08-20 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192386	2020-09-18 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-12-20 (122)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192396	2020-09-21 (32)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192397	2020-08-21 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192401	2021-02-12 (176)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3192405	2020-11-30 (102)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192410	2020-12-09 (110)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192412	2020-09-19 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3192414	2020-09-19 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192414	2020-09-19 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3192418	2020-12-09 (110)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3192422	2020-08-22 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192423	2020-10-10 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192425	2020-09-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192452	2020-08-24 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192454	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192456	2020-11-06 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192457	2021-01-23 (153)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192460	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192462	2020-09-18 (26)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3192476	2020-08-25 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3192483	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192486	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192493	2020-09-24 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192504	2020-09-19 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-18 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192511	2020-12-09 (105)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3192532	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192534	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192536	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192537	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192538	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3192539	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-05 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-08 (103)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192561	2020-09-22 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-16 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192566	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192585	2020-12-07 (101)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192590	2020-12-01 (95)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192594	2020-09-28 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192597	2020-11-02 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192602	2020-12-24 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192604	2021-02-08 (162)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3192627	2020-11-10 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192629	2020-12-01 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192652	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192661	2020-09-03 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192662	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192667	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192668	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192669	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192670	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192697	2020-10-11 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192707	2020-09-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192708	2020-10-12 (38)	Missing Endpoint Assessments Visit Scheduling	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window
US3192711	2020-09-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192712	2020-11-19 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192714	2020-11-19 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192715	2020-11-19 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192719	2020-11-17 (47)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192720	2020-10-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192731	2020-10-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192742	2021-02-09 (128)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3192750	2020-12-14 (69)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192757	2020-11-08 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192776	2020-10-11 (1)	Concomitant Medication Study Treatment Randomization	P09.01: Prohibited concomitant medication or vaccine received by subject P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192777	2020-10-11 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192778	2020-11-04 (25)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192780	2020-10-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-07 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192781	2020-10-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-20 (41)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3192784	2020-10-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3192792	2020-10-12 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-16 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192792	2020-11-20 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-04 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192794	2020-10-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192813	2020-10-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192814	2020-10-19 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192816	2020-11-14 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192820	2020-11-13 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192822	2020-11-12 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3192825	2020-10-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192828	2021-02-02 (111)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3192830	2020-10-15 (1)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3192838	2020-10-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192840	2020-11-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-17 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192841	2020-12-17 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3192843	2020-11-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192857	2020-11-19 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192865	2020-10-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192866	2020-11-21 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192893	2020-11-25 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3192894	2020-11-21 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3192902	2020-08-06 (-77)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3192906	2020-10-14 (-8)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2020-12-04 (44)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-09 (49)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-17 (57)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-15 (145)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit) P08.11: Subjects confirmed of COVID-19 not followed up for 28 days
US3192914	2020-12-28 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202001	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202011	2020-09-04 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202012	2020-09-11 (38)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3202015	2020-09-10 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202020	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202031	2020-09-14 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202036	2021-01-13 (161)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3202046	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-11 (36)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202048	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202053	2020-08-20 (14)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-08 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202054	2020-09-08 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3202069	2020-09-18 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202072	2020-09-15 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202073	2020-08-08 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-15 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202088	2020-08-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202091	2020-08-17 (9)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3202100	2020-09-11 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202101	2020-09-18 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202103	2020-09-17 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-30 (52)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-08 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3202107	2020-09-17 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202110	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202112	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202117	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202119	2020-09-18 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202120	2020-09-17 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202121	2020-09-18 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-28 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202130	2021-03-08 (210)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202135	2020-08-11 (-13)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-21 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202138	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-17 (37)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202139	2020-09-18 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202141	2020-09-30 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202142	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-17 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202142	2020-09-17 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202145	2020-08-12 (1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-09-23 (43)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-09 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202147	2020-09-25 (45)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202150	2020-09-22 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202156	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-26 (14)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up P07.07: Saliva sample not collected when required per protocol
US3202158	2020-10-22 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202163	2020-09-29 (48)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202173	2020-09-17 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202176	2020-09-18 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202177	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202178	2021-02-16 (187)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202186	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202191	2020-09-24 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202194	2020-09-25 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-10 (89)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202195	2020-09-25 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202197	2021-01-11 (150)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
	2021-03-11 (209)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3202198	2020-09-23 (40)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-10-07 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202200	2020-09-25 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202203	2020-09-19 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202204	2020-09-14 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202207	2020-09-21 (38)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202211	2020-10-22 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202212	2020-10-22 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202218	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202220	2020-09-25 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202229	2020-09-24 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202230	2020-10-22 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202232	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202233	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202236	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202244	2020-08-18 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202252	2020-09-17 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-22 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202254	2020-09-25 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202257	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202263	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202264	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-17 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3202269	2020-09-21 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202277	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3202279	2020-11-02 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202282	2020-10-29 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202287	2020-09-25 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202290	2020-09-22 (33)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3202294	2020-08-21 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-17 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202307	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202307	2020-09-22 (30)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3202310	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3202312	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-23 (91)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-03 (191)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3202318	2020-09-30 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202331	2020-09-04 (10)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202333	2020-09-24 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3202336	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202343	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-18 (23)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-20 (25)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202353	2020-12-03 (98)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3202355	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202358	2020-08-28 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-02 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3202359	2020-08-28 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3202367	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202375	2020-10-05 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3202378	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3202383	2020-10-07 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3202385	2020-10-12 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3202389	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3202391	2020-10-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3212003	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3212008	2021-03-01 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212010	2020-09-08 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-09 (219)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212013	2020-10-07 (66)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212013	2020-11-04 (94)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212016	2020-09-11 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-16 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-29 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212026	2020-09-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212028	2020-09-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3212034	2020-08-04 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3212039	2020-09-11 (39)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212050	2021-02-25 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212073	2020-09-10 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3212082	2021-03-12 (218)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212085	2021-03-03 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212105	2021-03-19 (222)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212111	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212118	2020-09-17 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-05 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212142	2021-02-22 (195)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212145	2021-03-08 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212146	2021-03-02 (203)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212148	2021-03-04 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212155	2021-03-11 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212157	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212158	2020-09-24 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212160	2020-09-22 (41)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3212177	2021-03-05 (204)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212179	2021-01-11 (151)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212179	2021-01-21 (161)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3212182	2021-03-18 (217)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212189	2021-03-05 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212191	2021-03-05 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212197	2021-03-05 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212200	2021-03-22 (218)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212226	2020-11-19 (94)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3212229	2021-03-03 (198)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212234	2021-03-05 (199)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212248	2021-03-16 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212252	2020-09-30 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3212265	2020-09-04 (16)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3212267	2021-03-11 (204)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3212283	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3212296	2020-11-15 (83)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3212331	2020-10-22 (53)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3212336	2021-02-02 (155)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3212374	2021-02-03 (147)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3212379	2020-11-12 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222004	2020-08-18 (13)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-10 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222007	2020-08-12 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222010	2020-09-07 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222012	2020-09-09 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222016	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222021	2020-09-05 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222027	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222028	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222035	2020-09-07 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-23 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3222039	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222040	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222041	2020-09-08 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222045	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-07 (31)	Inv Communication with Ethics Missing Endpoint Assessments	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements P07.10: Subject Diary not completed 30 min post dosing
US3222051	2020-08-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-05 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222054	2020-08-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-07 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222055	2020-09-08 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222062	2020-09-10 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222069	2020-09-15 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222079	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222083	2020-09-12 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-28 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222084	2020-09-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222085	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-02 (84)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222090	2020-09-10 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222094	2020-09-13 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222096	2020-11-02 (84)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222109	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222112	2020-09-11 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3222117	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-13 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222120	2020-09-15 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222126	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-11 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222133	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-10 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-11 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222136	2020-09-16 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3222137	2020-09-12 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-25 (135)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3222146	2020-09-13 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-20 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222150	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222154	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222164	2020-09-09 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222165	2020-09-09 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222167	2020-09-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222174	2020-09-09 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222186	2020-09-18 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222205	2020-09-17 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222212	2020-09-19 (33)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222217	2020-09-18 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222222	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222226	2020-08-21 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222231	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-23 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222232	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-23 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222233	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222234	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222234	2020-09-23 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222236	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222237	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-21 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222241	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-09 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222265	2020-09-17 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222269	2020-09-24 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222273	2020-09-28 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222274	2020-08-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-28 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222280	2021-01-16 (148)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3222286	2020-08-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222287	2020-08-19 (-3)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222291	2020-08-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-23 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222293	2020-08-23 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-03 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222299	2020-11-16 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222303	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222307	2020-09-26 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222312	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222319	2020-09-28 (36)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-29 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222323	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222325	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-01 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222337	2020-09-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222341	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222346	2020-10-09 (45)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3222353	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222364	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222370	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222373	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222375	2020-08-28 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
			P07.10: Subject Diary not completed 30 min post dosing
US3222379	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-04 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222380	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222383	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222383	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-21 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222384	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222387	2020-08-31 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3222388	2020-10-17 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222388	2020-12-07 (102)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222398	2020-08-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222400	2020-08-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222402	2020-09-22 (25)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222403	2020-12-08 (102)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222415	2020-11-10 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-12 (135)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-04 (158)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-03-15 (197)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222418	2020-12-18 (110)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222425	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222433	2020-11-02 (63)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222436	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222439	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222441	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222445	2020-09-30 (29)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-03-10 (190)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222449	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222458	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222459	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-02 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
			P07.10: Subject Diary not completed 30 min post dosing
US3222461	2020-10-02 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222462	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-11 (10)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-02 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222465	2020-09-07 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222468	2020-10-02 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222479	2020-11-13 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222482	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222492	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222498	2020-09-30 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222500	2020-10-08 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-30 (118)	Inv Qualifications/Agreements	I06.02: Unblinded personnel participated in other study aspects besides IP accountability, dose preparation and IP administration

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222501	2020-10-05 (32)	Missing Endpoint Assessments Study Procedures/Assessments	P07.10: Subject Diary not completed 30 min post dosing P08.01: Subject was not observed for at least 30 minutes after vaccination
US3222508	2020-09-05 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-05 (31)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3222515	2020-09-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222520	2020-09-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222534	2020-09-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222544	2020-10-06 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222556	2020-09-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3222568	2020-10-14 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222571	2020-10-01 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222572	2020-09-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-15 (36)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3222573	2020-09-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222576	2020-09-13 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222578	2020-10-16 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222579	2020-09-13 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222583	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-17 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222589	2020-10-16 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222591	2020-10-20 (39)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3222595	2020-09-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222595	2020-09-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-10 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-31 (49)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222596	2020-09-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-16 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3222601	2020-11-16 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222603	2020-09-19 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-15 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222608	2020-10-16 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222609	2020-11-02 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222612	2020-11-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222616	2020-09-18 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-22 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222617	2020-09-21 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222622	2020-10-20 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222625	2020-10-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222625	2020-11-05 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222627	2020-09-25 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3222629	2020-10-23 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222631	2020-09-25 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222633	2020-09-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-25 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-24 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222634	2020-09-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-26 (33)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222638	2020-10-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222639	2020-10-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222641	2020-09-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-01 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-09 (45)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3222643	2020-12-02 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222651	2020-11-05 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3222656	2020-10-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3222660	2020-10-02 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-02 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222664	2020-10-29 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3222665	2020-11-06 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232001	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232006	2020-08-06 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232009	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3232021	2020-09-09 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-09-11 (33)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232026	2020-08-13 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232033	2020-08-25 (14)	Data Privacy	I01.01: Breach of subject confidentiality
	2020-09-09 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-03-25 (226)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3232036	2020-09-14 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232038	2020-08-13 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-16 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232050	2020-09-11 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3232055	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232065	2020-08-18 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232077	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3232094	2020-08-22 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232095	2020-09-28 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232102	2020-08-25 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232118	2020-10-05 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232120	2020-08-28 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232121	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232127	2020-09-25 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232134	2020-10-01 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232142	2020-09-02 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3232151	2020-09-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232162	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232166	2020-10-17 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3232170	2020-09-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3232172	2020-10-17 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3232176	2020-10-16 (30)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3232178	2020-10-23 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3232181	2020-10-17 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3232183	2020-10-17 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242001	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3242016	2020-10-06 (61)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3242017	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3242032	2020-10-19 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242070	2020-08-19 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3242111	2020-09-18 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242129	2020-09-16 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3242131	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3242134	2020-08-23 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3242137	2020-09-16 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3242162	2020-11-02 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242163	2021-01-04 (138)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3242177	2020-09-28 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242194	2020-09-17 (25)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242194	2020-09-17 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242218	2020-09-01 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3242262	2020-10-03 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3242269	2021-01-22 (144)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3242343	2020-10-16 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3242357	2020-10-27 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242370	2020-11-17 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3242387	2020-12-01 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3242411	2020-11-02 (29)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error
US3242414	2020-11-01 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-09 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3242418	2020-11-07 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-10 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252003	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252004	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252007	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-29 (180)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252008	2020-08-29 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252010	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252016	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-03 (212)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252022	2021-03-01 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252024	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252025	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252033	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-02-23 (204)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252038	2021-03-06 (214)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252046	2020-09-03 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-02 (210)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252050	2021-03-02 (209)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252051	2020-12-09 (126)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-03-02 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252052	2020-08-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-08 (215)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252053	2020-08-06 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3252054	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-02 (209)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252058	2021-03-02 (209)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252068	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252069	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252075	2020-09-12 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252075	2020-10-23 (78)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
		Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2020-11-05 (91)	Study Procedures/Assessments	P08.11: Subjects confirmed of COVID-19 not followed up for 28 days P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3252081	2021-03-01 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252096	2021-03-05 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252101	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252102	2021-03-08 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252109	2020-12-09 (122)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-11 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-13 (126)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-06 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252110	2020-09-11 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252111	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-09 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252112	2021-03-10 (212)	Missing Endpoint Assessments Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol P08: Incorrect lab kit was used when part A and part B visit occur on same day
US3252124	2021-03-09 (211)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252126	2021-03-10 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252129	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-05 (207)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252140	2020-09-15 (35)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252141	2020-08-11 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252144	2020-08-12	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3252149	2021-03-05 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252156	2021-03-11 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252159	2021-03-09 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252166	2020-09-10 (29)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3252171	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252183	2021-03-17 (216)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-25 (224)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252185	2020-11-12 (91)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252192	2021-01-21 (160)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252206	2021-03-03 (199)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252208	2021-03-12 (208)	Missing Endpoint Assessments Study Procedures/Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol P08: Incorrect lab kit was used when part A and part B visit occur on same day
US3252209	2021-03-05 (201)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252220	2020-08-18 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-03-15 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252220	2021-03-15 (210)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252223	2020-09-16 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-22 (217)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252224	2021-03-18 (213)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252225	2021-03-15 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252236	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252237	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252257	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252259	2020-09-23 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252262	2021-01-08 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252265	2021-02-16 (181)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252269	2020-09-21 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252275	2020-09-23 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252277	2020-09-19 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-20 (212)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252278	2020-09-23 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252288	2020-09-19 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252294	2020-10-02 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252295	2021-03-11 (202)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252300	2021-03-20 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252306	2021-03-06 (197)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252313	2020-09-22 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252316	2020-09-25 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252317	2021-03-15 (204)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252323	2021-03-17 (206)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252324	2020-12-08 (107)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3252330	2021-03-22 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252331	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252331	2020-09-24 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252338	2021-03-22 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252344	2021-03-24 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252352	2020-10-16 (52)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3252354	2020-09-28 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252357	2021-03-23 (208)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252368	2020-09-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252378	2020-09-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252379	2021-02-13 (169)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252380	2021-03-25 (209)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252412	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252419	2020-11-06 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252426	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3252450	2021-02-05 (149)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252464	2020-09-23 (13)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252475	2021-03-12 (180)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3252481	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-12 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-17 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252484	2020-09-24 (10)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252489	2020-10-24 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3252493	2021-03-26 (192)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3252509	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252515	2020-09-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252516	2020-10-20 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252527	2020-09-25 (4)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252545	2020-10-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252569	2020-09-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252578	2021-02-02 (128)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3252613	2020-10-03 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3252621	2020-11-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3252625	2020-10-06 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252649	2020-10-20 (11)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3252664	2021-03-05 (143)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3252667	2020-11-10 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252671	2021-01-01 (79)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3252673	2020-11-10 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3252678	2020-12-16 (62)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-20 (66)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3252678	2020-12-30 (76)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-03-05 (141)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Visit Scheduling	P07.06: Nasopharyngeal swab sample not collected when required per protocol P10.01: Onsite Visits not performed or out of window
US3252683	2020-10-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252686	2020-10-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3252697	2021-02-03 (105)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3262002	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262003	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262004	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262008	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262010	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262015	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262016	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262018	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262019	2020-07-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262026	2020-07-31 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-03 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262027	2020-09-21 (56)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262028	2020-09-24 (58)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262029	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262034	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262035	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262036	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262041	2020-07-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262044	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262046	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262049	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262052	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262058	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262061	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262062	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262065	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262071	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262072	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262076	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262079	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262080	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-09 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262085	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262090	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262092	2021-03-18 (227)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262098	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262100	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262102	2020-08-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262102	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262104	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262106	2021-03-23 (231)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262107	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262110	2020-09-16 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262115	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262117	2020-09-08 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262119	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262123	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262124	2020-08-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3262125	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262134	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-16 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262135	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262137	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262139	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262141	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262147	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262150	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262155	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262167	2020-10-20 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262171	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3262173	2020-10-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262182	2020-09-17 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-09-18 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262189	2020-09-21 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262190	2020-09-29 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262191	2020-09-20 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262206	2020-08-18 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262206	2020-09-25 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262220	2020-08-20 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-17 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3262226	2020-10-20 (61)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3262231	2020-09-23 (34)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3262247	2020-10-02 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3262248	2020-09-30 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3262266	2020-10-15 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-12 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3262270	2021-01-14 (101)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3272001	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-08-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3272003	2020-07-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-31 (34)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3272011	2020-07-29	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3272013	2020-07-30 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2020-09-03 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
			P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272027	2020-09-24 (55)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3272051	2020-09-06 (33)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-08 (35)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-10 (37)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-09-12 (39)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3272057	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3272074	2020-08-07 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-16 (71)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3272093	2020-09-11 (33)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3272109	2020-08-07 (-5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272109	2020-08-12 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3272120	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3272137	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272139	2020-08-13 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-15 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3272140	2020-09-15 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272160	2020-09-01 (18)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-14 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272160	2021-01-13 (152)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3272165	2021-01-06 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3272170	2020-10-22 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272178	2020-08-20 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3272180	2021-02-15 (182)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3272199	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-14 (56)	Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-16 (58)	Study Procedures/Assessments	P07.07: Saliva sample not collected when required per protocol
US3272231	2020-09-30 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272237	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-02 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272241	2020-08-21 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3272260	2020-08-22 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3272263	2020-09-30 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272275	2020-08-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3272294	2020-08-22 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-22 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-27 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272338	2020-08-23 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-09-22 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3272360	2020-11-03 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3272363	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3272364	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3272369	2020-12-05 (93)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results
US3272371	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-14 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3272373	2020-10-06 (16)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3272377	2020-11-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3272379	2020-11-25 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3282019	2020-09-03 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3282027	2020-09-08 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3282028	2020-09-08 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3282042	2020-09-14 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-13 (154)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3282047	2020-09-11 (30)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3282073	2020-09-21 (32)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3282100	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3282113	2020-11-19 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3292023	2020-11-06 (95)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3292025	2021-03-05 (214)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3292032	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3292044	2020-08-28 (23)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3292055	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292056	2020-08-28 (21)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3292061	2020-10-13 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3292065	2020-11-06 (91)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292068	2020-09-17 (41)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292069	2021-01-30 (176)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292077	2020-09-08 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3292087	2020-10-16 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3292114	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292129	2020-09-17 (38)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3292142	2020-11-06 (86)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292145	2020-08-28 (16)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff I02.05: Informed consent not signed prior to any study procedure
US3292185	2020-12-21 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3292193	2021-02-04 (174)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292197	2020-11-06 (84)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292225	2020-11-04 (79)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292241	2020-09-20 (32)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-10-27 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-04 (77)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-24 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-04 (169)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292252	2020-11-04 (77)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3292304	2021-02-04 (164)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3292305	2020-11-14 (82)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-04 (164)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292310	2020-11-07 (75)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292392	2020-12-10 (87)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3292406	2021-01-28 (129)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3292412	2020-12-10 (78)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-20 (88)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292413	2021-01-11 (110)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-16 (115)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-17 (116)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3292417	2020-11-06 (44)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-26 (125)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3292420	2020-11-06 (44)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292430	2020-12-03 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-13 (105)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292431	2021-01-22 (114)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3292435	2020-11-06 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3292450	2020-12-30 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3302003	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302004	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302005	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-06 (4)	Missing Endpoint Assessments	P07.03: Subject diary has 2 or more consecutive days of solicited entries missing within one segment (Post Dose 1)
US3302013	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302024	2021-01-12 (162)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302034	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302045	2020-10-06 (63)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302049	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302082	2021-01-07 (155)	Study Treatment Admin/Dispense	P05.13: Subject received more than 2 doses of mRNA-1273
US3302109	2020-08-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302111	2020-09-10 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-13 (67)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3302116	2020-12-23 (136)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3302123	2020-09-10 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302139	2020-10-07 (58)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302139	2021-01-05 (148)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302141	2021-01-08 (151)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302144	2021-01-08 (151)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302145	2020-10-06 (57)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302151	2021-01-12 (154)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302156	2021-01-12 (154)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302168	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-14 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302169	2021-01-12 (154)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302183	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3302188	2020-09-10 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (54)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-08 (149)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302203	2020-09-14 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302212	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302225	2021-01-12 (149)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302237	2020-09-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302258	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3302292	2021-02-16 (181)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3302299	2021-01-12 (146)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302308	2021-01-12 (146)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302326	2020-09-23 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302328	2021-01-12 (145)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302343	2020-09-21 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3302355	2021-01-12 (140)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302365	2020-09-26 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302386	2020-09-25 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302387	2020-09-25 (31)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302401	2021-01-12 (139)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302413	2020-10-21 (55)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302422	2021-01-08 (134)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302431	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3302434	2021-01-12 (138)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3302441	2020-09-28 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3302444	2021-01-12 (135)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302451	2021-01-12 (120)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302456	2020-11-16 (57)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302474	2020-11-13 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3302475	2021-01-12 (91)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3302476	2020-11-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-20 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312014	2020-09-06 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312051	2020-09-08 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3312063	2020-09-10 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3312170	2020-08-18 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312197	2020-10-05 (47)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3312213	2020-10-09 (50)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3312246	2020-09-20 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312304	2020-08-26 (-2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312328	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312338	2020-08-26 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3312358	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3312441	2021-02-25 (178)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3312442	2020-11-04 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3312528	2020-09-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3312529	2020-10-05 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3312562	2020-10-07 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3312637	2020-10-09 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3322007	2021-02-01 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322008	2021-01-25 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322010	2021-01-28 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322015	2020-09-17 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3322018	2020-08-23 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3322023	2020-10-21 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322023	2020-10-22 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-23 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322029	2020-09-25 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3322038	2021-01-19 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322043	2021-01-18 (153)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322050	2020-09-28 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3322051	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3322062	2020-09-18 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3322092	2020-09-17 (24)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322113	2020-10-08 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3322126	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3322127	2020-10-30 (63)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3322128	2020-10-05 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3322131	2020-09-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3322132	2020-09-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3322140	2021-01-12 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322145	2021-01-11 (134)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322155	2020-10-05 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-18 (140)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322158	2021-01-07 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-02-01 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322169	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3322179	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3322187	2020-10-27 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322201	2020-09-17 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3322207	2021-02-01 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322216	2021-01-21 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322217	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3322224	2021-01-21 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322232	2020-10-15 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-19 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322235	2021-01-23 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322236	2021-01-22 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322241	2021-01-25 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322248	2020-09-17 (10)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-02 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322252	2021-01-11 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322253	2021-01-16 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322254	2021-01-14 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322257	2021-01-19 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322265	2021-01-23 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322267	2021-01-25 (139)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322271	2021-01-27 (141)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322272	2021-03-03 (176)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322279	2020-10-09 (31)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3322280	2021-01-20 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322282	2021-01-15 (129)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322288	2020-11-23 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322289	2020-10-08 (30)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3322291	2020-11-23 (76)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3322292	2021-01-25 (139)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322293	2020-09-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-03 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3322302	2021-01-26 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322306	2021-01-21 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322308	2021-02-01 (143)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322310	2021-01-12 (124) 2021-01-14 (126)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322311	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3322312	2020-09-25 (15) 2021-01-25 (137)	Concomitant Medication ICF Process/Timing Study Procedures/Assessments	P09.01: Prohibited concomitant medication or vaccine received by subject I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322314	2021-01-25 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322315	2021-01-21 (133)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322317	2021-01-18 (130)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322319	2020-09-17 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-18 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-23 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322320	2021-01-16 (128)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322321	2021-01-23 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322322	2021-03-24 (195)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322324	2020-09-17 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3322328	2021-01-25 (136)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322329	2021-01-21 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322332	2020-11-05 (55)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-20 (131)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322336	2020-12-01 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-26 (113)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3322344	2020-11-06 (54)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3322355	2021-01-18 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322357	2021-01-11 (117)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322358	2021-01-22 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322373	2021-01-12 (117)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322374	2021-01-16 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322375	2021-02-08 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322382	2021-01-22 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322384	2021-01-26 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322387	2020-10-02 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-12 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-14 (46)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3322393	2021-01-25 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322401	2020-11-24 (56)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-14 (107)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3322417	2020-12-01 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3322424	2020-10-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3322429	2021-02-03 (113)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3332006	2020-09-12 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3332009	2020-08-31 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3332010	2020-08-31 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3332031	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3332059	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3332061	2020-10-19 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3332076	2020-09-08 (7)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3332102	2020-08-17 (-60)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342017	2020-12-30 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3342035	2020-11-23 (104)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3342096	2020-08-21 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342102	2020-09-25 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342119	2020-09-21 (34)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3342121	2020-09-27 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342127	2020-08-22 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342138	2020-09-23 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342139	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342151	2020-10-13 (47)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-16 (201)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3342160	2020-10-03 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342161	2020-10-12 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-14 (44)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342164	2020-09-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342164	2020-10-12 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342165	2020-10-13 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342167	2020-09-04 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342181	2020-10-12 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342189	2020-10-21 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342191	2020-10-12 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342193	2020-10-06 (33)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3342205	2020-10-15 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342215	2020-12-08 (91)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342225	2020-10-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342232	2020-09-14 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342239	2020-10-13 (34)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3342254	2020-10-20 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342287	2020-10-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342296	2020-09-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342314	2020-11-06 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3342322	2020-12-16 (65)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3342324	2020-12-18 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3342326	2020-10-13 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3342347	2020-11-17 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3342356	2021-01-21 (102)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3352005	2020-08-10 (7)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352011	2020-12-01 (120)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3352015	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3352016	2020-08-12 (9)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352027	2021-03-02 (209)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352028	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352030	2020-08-31 (26)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352039	2021-03-17 (224)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352052	2020-09-17 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-02 (84)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352101	2020-08-18 (1)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-08-20 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352104	2020-08-19 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-20 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352110	2020-12-29 (134)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352118	2020-09-19 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3352155	2020-11-03 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (112)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352163	2020-11-02 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-03 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (112)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352169	2020-09-29 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-02 (75)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352170	2020-08-21 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352176	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352177	2021-01-13 (145)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352183	2021-01-11 (143)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352184	2021-02-08 (171)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352194	2020-09-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352195	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352205	2020-10-26 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352207	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352208	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352214	2021-02-03 (166)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352215	2020-09-29 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-02 (73)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352216	2021-03-11 (202)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352223	2020-12-28 (129)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-16 (148)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352230	2020-09-19 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3352234	2020-10-01 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-29 (127)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352238	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352244	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-03 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (107)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352250	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-20 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352250	2020-11-02 (70)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352253	2021-01-16 (145)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352255	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352257	2021-01-06 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352267	2021-02-13 (173)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352268	2021-01-16 (145)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352271	2020-09-26 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352273	2020-09-08 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352283	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352284	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-29 (97)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352299	2020-12-08 (99)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352313	2020-09-11 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352317	2020-09-16 (7)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352323	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-12 (3)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3352326	2020-09-14 (5)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352328	2020-09-12 (3)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352333	2020-09-13 (4)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3352338	2020-10-16 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-26 (139)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352340	2020-09-15 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-12 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352343	2021-01-19 (132)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352348	2021-01-13 (126)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352358	2020-10-15 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-09 (91)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352359	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-15 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352369	2020-10-08 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-12 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352370	2020-09-12 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352371	2020-09-19 (10)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352374	2020-11-17 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352387	2021-01-06 (110)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3352389	2020-09-24 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-03 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352394	2020-10-21 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352412	2020-11-03 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-09 (77)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352436	2020-11-01 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352437	2020-10-30 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352437	2020-12-01 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352439	2021-03-15 (168)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3352443	2020-09-29 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-09 (72)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352446	2020-11-04 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352451	2020-10-01 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352455	2020-11-05 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3352458	2020-12-17 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352461	2020-10-01 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352474	2020-10-03 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-09 (72)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352477	2020-10-02 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-12 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-16 (49)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-10 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352478	2020-12-10 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352484	2020-09-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3352491	2020-10-20 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-09 (65)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352492	2020-10-10 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352498	2020-12-09 (65)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352506	2020-10-08 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-09 (65)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352507	2020-11-12 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352512	2020-10-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3352513	2020-12-17 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3352514	2020-12-09 (63)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352522	2020-10-10 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352525	2020-11-06 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352529	2020-10-09 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-07 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-26 (111)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3352533	2020-12-23 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352543	2020-12-09 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352544	2020-10-15 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352549	2020-10-15 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-12-09 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352569	2020-12-09 (56)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352570	2020-10-15 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3352571	2020-10-18 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3352575	2020-11-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352579	2020-11-15 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3352586	2020-10-19 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3352593	2020-12-09 (49)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352594	2020-12-09 (49)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3352596	2020-12-09 (49)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362007	2021-02-27 (211)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-04 (216)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3362008	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362011	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3362015	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3362016	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3362022	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3362023	2020-09-10 (39)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362057	2020-08-06 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362059	2020-08-06 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362060	2020-08-06 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
	2021-01-06 (154)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362063	2020-08-04 (-2) 2020-08-06 (1)	Data Privacy Study Treatment Admin/Dispense	I01.01: Breach of subject confidentiality P05.10: IP stored outside the required temperature range and administered to a subject
US3362064	2020-08-06 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362066	2020-08-06 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362068	2020-08-06 (1) 2020-09-03 (29)	Study Treatment Admin/Dispense Missing Endpoint Assessments	P05.10: IP stored outside the required temperature range and administered to a subject P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362071	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362081	2020-09-10 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362086	2020-09-12 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3362093	2020-10-27 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362107	2020-08-11 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362109	2020-08-11 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362112	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
	2021-01-08 (151)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3362114	2020-08-12 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362115	2020-08-12 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362116	2020-08-12 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
	2020-09-18 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362121	2020-08-12 (1)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3362128	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362129	2020-09-22 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362136	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362148	2020-08-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-23 (40)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3362158	2020-09-23 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-29 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3362161	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362164	2020-08-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362203	2020-09-24 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362204	2020-10-05 (47)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3362215	2020-10-20 (61)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3362222	2020-08-28 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3362246	2020-09-25 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362250	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3362257	2020-10-02 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-02 (99)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3362275	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3362289	2020-09-23 (-3)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3372002	2020-08-03 (-1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372007	2020-08-03 (-1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-01 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372009	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-27 (25)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372012	2020-08-03 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372013	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372016	2020-10-19 (78)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3372018	2020-08-03 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372018	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-04 (155)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3372019	2020-08-03 (-17)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3372022	2020-08-03 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-04 (2)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372031	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372034	2021-02-19 (199)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372039	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372044	2020-09-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372074	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372081	2020-09-07 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372082	2020-10-29 (80)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3372084	2020-09-14 (35)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-03 (54)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372127	2020-09-20 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372128	2020-09-10 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372147	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372151	2020-10-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372165	2020-09-12 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372180	2020-09-23 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372187	2020-09-21 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372222	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372241	2020-11-25 (93)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372246	2020-09-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372262	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372270	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372273	2021-03-22 (208)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3372285	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372286	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372306	2020-09-30 (30)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-11-25 (86)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372313	2020-10-12 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372315	2021-01-11 (132)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3372328	2020-10-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372331	2020-10-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372350	2020-09-11 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3372355	2020-11-23 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372364	2020-10-23 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-23 (169)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3372380	2020-10-19 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372380	2020-10-22 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3372420	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3372426	2020-10-22 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3372430	2020-10-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3372444	2020-09-26 (6)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3372447	2020-09-25 (4)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3372454	2020-10-15 (21)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3372457	2020-09-30 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3372486	2020-11-25 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382002	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3382005	2020-08-21 (12)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3382008	2020-08-09	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3382010	2020-12-19 (132)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382018	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3382029	2020-12-19 (128)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382040	2020-12-17 (123)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382061	2020-09-25 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3382067	2020-09-24 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382080	2020-09-25 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3382090	2020-09-25 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382103	2020-10-28 (66)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3382109	2020-10-01 (38)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382115	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3382123	2020-08-27 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3382125	2020-08-27 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3382129	2020-08-27 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3382132	2020-08-27 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-12-18 (114)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382134	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382151	2020-08-31 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3382168	2020-10-02 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382190	2020-09-11 (9)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3382192	2020-09-04 (2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3382204	2020-09-08 (5) 2021-01-21 (140)	ICF Process/Timing Study Procedures/Assessments	I02.02: Wrong informed consent version signed P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3382209	2020-12-23 (111)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3382216	2020-09-08 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3382219	2020-09-08 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382220	2020-09-08 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3382235	2020-10-09 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-01-18 (131)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3382243	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-19 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3382262	2020-10-18 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3382267	2020-10-14 (33)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3382271	2021-01-08 (119)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3382283	2020-11-06 (52)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3382284	2020-09-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3382293	2020-10-30 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3382294	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-31 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3392002	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-18 (38)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392021	2020-10-19 (67)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3392022	2020-09-08 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392032	2020-09-11 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392035	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392059	2020-08-19 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-13 (25)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392063	2020-08-20 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3392077	2020-09-23 (30)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392085	2020-09-23 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392086	2020-09-23 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392088	2020-09-22 (28)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392109	2020-09-22 (26)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392114	2020-08-27 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392126	2020-09-25 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392128	2020-09-02 (3)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392133	2020-09-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392149	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-12 (11)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-06 (35)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392158	2020-09-02 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392161	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392162	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392164	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-28 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392167	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-30 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392174	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392183	2020-09-08 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-06 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392186	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392187	2020-09-29 (21)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392189	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392190	2020-11-12 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3392196	2020-10-07 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392198	2020-10-09 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392203	2020-10-07 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392206	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392207	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-21 (42)	Missing Endpoint Assessments Visit Scheduling	P07.10: Subject Diary not completed 30 min post dosing P10.01: Onsite Visits not performed or out of window
US3392223	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392227	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392241	2020-10-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392243	2020-12-11 (92)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3392247	2020-09-11 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392261	2020-11-17 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3392263	2020-12-23 (103)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392264	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392268	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3392278	2020-10-09 (26)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392278	2020-10-09 (26)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-30 (47)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3392288	2020-10-16 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392297	2020-09-15 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-12 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392303	2020-09-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-13 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392306	2020-09-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392324	2020-11-18 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3392328	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392336	2020-09-09 (-9)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3392342	2020-09-23 (1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3392343	2020-09-29 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3392349	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3392350	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-13 (13)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402003	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402005	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402006	2020-07-26 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-01 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402012	2020-10-21 (87)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402014	2020-08-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402015	2020-07-30 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402015	2020-08-26 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402017	2020-07-27 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402025	2020-07-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402032	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402034	2020-07-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402041	2020-08-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402049	2020-08-29 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402051	2020-07-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402059	2020-08-25 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-08-29 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402073	2020-09-09 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3402075	2020-07-28 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402079	2020-08-28 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402081	2020-08-26 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402093	2020-08-27 (30)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402103	2020-08-27 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402122	2020-08-28 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3402151	2020-09-05 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402152	2020-07-31 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402156	2020-07-31 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402158	2020-10-27 (88)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402159	2020-07-31 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402177	2020-08-01 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402178	2020-08-01 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402179	2020-08-31 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402181	2020-09-10 (40)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3402189	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402191	2020-09-10 (40)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3402193	2020-09-03 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402205	2020-08-03 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3402212	2020-08-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-04 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-09 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-13 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3402218	2020-09-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402220	2020-08-25 (22)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402228	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402237	2020-09-02 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402244	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402297	2021-01-06 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3402303	2020-09-11 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402316	2020-10-25 (78)	Inv Safety Rptg (Reg/Sponsor)	I12.02: Pregnancy not reported within 24 hours of site awareness
	2020-11-09 (93)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402318	2020-09-11 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402354	2020-08-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402360	2020-09-08 (25)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-08 (55)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402360	2020-10-21 (68)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402372	2020-08-21 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3402379	2021-01-28 (166)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3402411	2020-09-22 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-21 (154)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3402412	2020-10-08 (49)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402416	2020-10-26 (66)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3402428	2020-09-11 (21)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402442	2020-09-07 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3402443	2020-09-09 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3402447	2020-11-20 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402450	2020-11-19 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402457	2020-11-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3402466	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3402477	2020-10-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402479	2020-10-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3402481	2020-10-23 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3412002	2020-08-20 (24) 2020-08-21 (25)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412006	2020-08-21 (24)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412007	2020-08-21 (24)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412009	2020-08-21 (24) 2020-08-29 (32)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412013	2020-08-21 (24)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412014	2020-08-21 (24) 2020-08-25 (28)	ICF Process/Timing Concomitant Medication	I02.02: Wrong informed consent version signed P09.01: Prohibited concomitant medication or vaccine received by subject
US3412015	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412016	2020-08-21 (24)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412017	2020-08-21 (24) 2021-02-19 (206)	ICF Process/Timing Concomitant Medication	I02.02: Wrong informed consent version signed P09.01: Prohibited concomitant medication or vaccine received by subject
US3412019	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412021	2020-08-21 (24) 2020-09-01 (35)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412023	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412029	2020-09-16 (50)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412032	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412034	2020-07-30 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412035	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412037	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412038	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412039	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412041	2020-07-30 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-09-03 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412042	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412045	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412046	2020-09-16 (49)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412052	2020-07-30 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412053	2020-08-21 (23)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412054	2020-07-30 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412057	2020-08-21 (22)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412058	2020-09-21 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-22 (84)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412059	2020-08-21 (22)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412062	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-09-11 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3412065	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412067	2020-12-02 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412069	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412070	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412071	2020-10-13 (75)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412072	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412077	2020-08-21 (22)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412079	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412083	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412085	2020-07-31 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412088	2020-08-21 (22)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412090	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-13 (68)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412091	2020-08-21 (16)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412096	2020-08-27 (22)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-07 (63)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412100	2020-08-03 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412101	2020-08-03 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-09-25 (54)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412102	2020-08-03 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412109	2020-10-06 (65)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412110	2020-09-16 (45)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412112	2020-08-03 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412113	2020-08-03 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412114	2020-08-21 (18)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412115	2020-08-04 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412116	2020-08-04 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412117	2020-08-04 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412119	2020-08-04 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412121	2020-09-16 (44)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412124	2020-08-04 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412125	2020-10-07 (65)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-22 (172)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412126	2020-09-02 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-07 (65)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-24 (205)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3412127	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412128	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412129	2020-08-24 (20)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-08-27 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-07 (64)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412131	2020-08-05 (1)	ICF Process/Timing Study Treatment Randomization	I02.02: Wrong informed consent version signed P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412135	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412136	2020-08-21 (17)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412138	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412143	2020-09-16 (24) 2020-11-15 (84)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.07: Saliva sample not collected when required per protocol
US3412144	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412145	2020-08-05 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412147	2020-08-05 (1) 2020-08-18 (14) 2020-09-15 (42)	ICF Process/Timing Accidental Unblinding Study Treatment Admin/Dispense Visit Scheduling	I02.02: Wrong informed consent version signed P12.01: Inadvertent unblinding of site personnel P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3412150	2020-09-16 (30)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412151	2020-08-06 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412153	2020-08-21 (16)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412159	2020-12-30 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412161	2020-08-06 (1) 2020-09-24 (50)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412161	2020-09-24 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3412163	2020-10-13 (68)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412165	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412167	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412172	2020-08-07 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2020-08-14 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-03 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3412174	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412176	2020-09-16 (41)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412182	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412186	2020-12-30 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412187	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412188	2020-09-16 (38)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-01-16 (160)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-18 (162)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3412189	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412193	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412194	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412195	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412196	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412199	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412200	2020-09-13 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412203	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412204	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412206	2020-09-16 (37)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412207	2020-10-13 (64)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412209	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412213	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412215	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412216	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412217	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412218	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412231	2021-01-11 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412244	2020-10-22 (70)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3412249	2020-09-14 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3412272	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3412329	2020-10-22 (58)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3412352	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3412370	2020-10-12 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3412381	2020-12-30 (72)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3412383	2020-10-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3412385	2020-10-27 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-05 (107)	Study Treatment Admin/Dispense	P05.07: Subsequent vaccine administered while contraindicated for a visit (e.g.: Pre-Vaccination Body Temperature =38.0°C/100.4°F)
US3422008	2020-08-12 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422046	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3422057	2020-09-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-30 (43)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3422069	2020-09-25 (37)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3422072	2020-09-16 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422073	2020-09-16 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422090	2020-10-06 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3422093	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422135	2020-10-06 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422169	2020-10-01 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422183	2020-10-15 (44)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3422202	2020-11-06 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422228	2020-10-07 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422236	2020-11-10 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3422244	2020-10-07 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422246	2020-10-11 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3422252	2020-10-08 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3422274	2020-11-20 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3422295	2020-11-20 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432010	2020-09-01 (29)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3432019	2020-08-08 (4)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3432022	2020-08-08 (4)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-12 (161)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3432032	2020-09-09 (35)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432034	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3432040	2020-09-28 (54)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3432042	2020-08-08 (3)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3432043	2020-08-10 (5)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3432054	2020-10-08 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432064	2021-03-11 (216)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3432076	2020-08-19 (10)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432083	2020-08-22 (6)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)
	2020-08-28 (12)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432111	2020-09-20 (40)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3432119	2020-08-12 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3432129	2020-08-13 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3432132	2020-09-10 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432176	2020-08-17 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432193	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3432240	2020-09-01 (11)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432241	2020-09-16 (26)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3432261	2020-10-02 (40)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-08 (46)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-10 (140)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432269	2021-02-16 (177)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-17 (206)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432272	2020-09-18 (26)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3432286	2021-03-19 (207)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432288	2020-09-28 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3432334	2020-09-28 (32)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-17 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3432349	2020-09-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432389	2020-09-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432398	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432406	2020-09-09 (8)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432417	2021-01-22 (142)	Data Privacy	I01.01: Breach of subject confidentiality
US3432425	2020-10-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3432436	2020-10-21 (48)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432447	2020-12-01 (88)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3432458	2020-09-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3432465	2021-02-15 (161)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432471	2020-11-24 (77)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3432474	2020-10-19 (41)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-02 (55)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432488	2020-10-14 (34)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432495	2020-10-23 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432513	2020-09-23 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3432518	2020-12-08 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432531	2020-10-22 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-29 (41)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-11-20 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432552	2020-12-09 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432560	2021-02-12 (141)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3432565	2020-10-13 (18)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-27 (124)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432582	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432586	2020-10-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3432589	2020-10-15 (11)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3432601	2020-12-15 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432606	2020-10-15 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-14 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432615	2021-01-06 (83)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
US3432619	2020-10-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3432619	2020-11-25 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432627	2020-11-20 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3432628	2021-02-03 (106)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3432631	2020-10-21 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3432641	2021-01-08 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3442001	2020-08-12 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3442002	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442002	2020-08-26 (14)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-10 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442006	2020-08-12 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3442010	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-08 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442016	2020-09-10 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3442018	2020-10-21 (69)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3442021	2020-08-17 (-1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442030	2020-08-17 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442031	2020-08-17 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442035	2020-08-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442038	2020-08-19 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3442041	2020-12-29 (132)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3442047	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442055	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442055	2020-10-09 (50)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3442058	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442059	2020-12-27 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3442070	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442073	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442078	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3442081	2020-10-07 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442086	2020-08-31 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3442087	2020-10-21 (58)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-02-22 (182)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3442088	2021-01-19 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3442094	2020-09-23 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-18 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3442105	2021-01-15 (141)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3442125	2020-09-23 (20)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3442143	2020-09-13 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442147	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3442156	2020-10-20 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442165	2020-10-21 (37)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3442199	2020-10-21 (34)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3442223	2020-10-13 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3442226	2020-10-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-10 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-11 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3442231	2020-11-10 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3442245	2021-02-12 (116)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3452002	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452005	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452008	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452009	2020-07-29 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3452024	2021-01-11 (166)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3452039	2021-01-20 (175)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3452063	2020-11-18 (111)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452071	2021-01-13 (167)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452075	2020-08-07 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452094	2021-01-11 (164)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3452127	2020-10-21 (80)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3452170	2020-12-23 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452192	2020-08-09 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452196	2021-02-09 (190)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452196	2021-02-09 (190)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452205	2020-09-09 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452218	2020-08-04 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-17 (135)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452231	2020-09-06 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452246	2020-08-04 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-12 (220)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452268	2021-01-19 (167)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452300	2020-09-05 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452304	2020-10-01 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3452329	2020-09-09 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452334	2020-09-23 (31)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3452351	2020-09-26 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3452362	2020-10-17 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452363	2020-09-16 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3452367	2020-10-15 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3452370	2020-10-13 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452375	2020-09-23 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452378	2020-09-25 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452381	2020-09-23 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452384	2020-10-22 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3452392	2020-09-24 (2)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-26 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452395	2020-09-23 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3452397	2020-09-25 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3452398	2021-01-19 (118)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3452413	2020-11-23 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462003	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-12 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462010	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3462013	2020-09-21 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462016	2020-09-08 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462022	2020-08-03 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462025	2020-09-09 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-14 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462026	2020-08-03 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462035	2020-08-04 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462035	2020-09-17 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-07 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462047	2020-09-04 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462048	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3462083	2020-10-09 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462087	2020-09-16 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462096	2020-10-08 (60)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462097	2020-10-08 (60)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462105	2020-08-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462107	2020-09-15 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462110	2020-08-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462113	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3462124	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462137	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3462144	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3462146	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3462154	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462157	2020-09-30 (50)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462171	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462185	2020-09-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462206	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462213	2020-09-30 (45)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-14 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462225	2020-09-17 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462233	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3462239	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462254	2020-09-17 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462262	2020-09-17 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462270	2021-02-02 (167)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-05 (170)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462277	2020-10-09 (51)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462282	2020-10-23 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462294	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3462300	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-12 (201)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3462337	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3462345	2020-10-29 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462351	2021-02-12 (171)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3462353	2020-10-02 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3462362	2020-10-07 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462379	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-15 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3462392	2020-11-09 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3462416	2021-02-26 (176)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3472010	2020-09-03 (2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-02 (62)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472016	2020-11-02 (60)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3472017	2020-10-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3472021	2020-09-16 (-5)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3472027	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3472031	2020-11-24 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3472033	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-07 (119)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-02-04 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472034	2020-12-02 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3472040	2020-10-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3472048	2020-10-22 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3472059	2021-03-09 (173)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472076	2020-09-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3472089	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3472091	2020-11-02 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3472091	2020-11-02 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3472094	2020-11-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3472097	2020-11-05 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3472101	2020-10-09 (1)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3472103	2020-10-09 (1)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482004	2020-12-22 (135)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482031	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3482032	2020-10-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3482049	2021-02-12 (183)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482050	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-03-24 (223)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3482053	2020-09-11 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-07 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482062	2020-08-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482064	2020-10-15 (60)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3482113	2020-09-18 (29)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482126	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3482140	2020-09-23 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3482155	2020-09-17 (22)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3482184	2020-09-02 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3482192	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3482242	2020-10-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3482279	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3482284	2020-12-03 (49)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3482287	2020-12-22 (71)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482296	2021-02-10 (119)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482308	2020-10-20 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3482309	2021-01-22 (95)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3482316	2020-11-12 (23)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3482323	2021-01-08 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3492002	2021-01-14 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492003	2020-09-21 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-12 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492006	2020-08-25 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-11 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492009	2020-08-30 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-12 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492010	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492011	2021-01-12 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492012	2021-01-12 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492022	2020-09-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-12 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492023	2020-08-28 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492023	2020-09-25 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-09 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3492024	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2021-01-19 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492025	2021-01-11 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492029	2020-08-31 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-09-29 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-12 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-12 (194)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3492032	2021-01-13 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492036	2021-01-20 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492037	2021-01-19 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492038	2021-01-12 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492039	2021-01-11 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492040	2020-09-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-21 (112)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-15 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492041	2020-09-01 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-29 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3492047	2020-09-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-11 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492053	2020-12-21 (110)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-13 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492055	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492056	2020-10-02 (30)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-01-19 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492057	2021-01-15 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492058	2021-01-15 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492061	2021-01-20 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492062	2021-01-12 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492063	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-13 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492066	2021-01-14 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492069	2020-10-14 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-11 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492070	2021-01-20 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492072	2021-01-15 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492073	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-09 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-12 (190)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3492076	2021-01-15 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492077	2021-01-15 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492078	2020-09-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-15 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-12 (189)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3492084	2020-09-08 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3492087	2020-12-08 (92)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492095	2020-12-15 (99)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3492098	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-20 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492102	2021-01-15 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492103	2020-10-07 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-19 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492107	2020-10-07 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3492108	2021-01-21 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492109	2021-01-14 (128)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492113	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-08 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3492121	2021-01-14 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492123	2020-09-22 (12)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-08 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492133	2021-01-15 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492135	2021-01-12 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492136	2021-01-08 (119)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492139	2020-10-13 (32)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3492143	2021-01-20 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492143	2021-03-13 (183)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3492151	2020-10-12 (29)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3492155	2021-03-12 (179)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3492157	2021-01-15 (123)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492163	2021-01-14 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492164	2020-10-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-13 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492166	2021-01-14 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492170	2021-01-12 (119)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492175	2021-01-11 (118)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492179	2021-01-19 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492180	2021-01-15 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492183	2021-01-21 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492191	2021-01-19 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492192	2021-01-21 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492193	2021-01-13 (118)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492195	2020-09-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3492196	2021-01-20 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492203	2021-01-21 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492210	2021-01-13 (117)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492212	2021-01-14 (118) 2021-01-22 (126)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol
US3492215	2020-11-20 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3492216	2021-01-12 (116)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492221	2021-01-20 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492222	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3492223	2021-01-19 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492226	2020-10-20 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492235	2020-10-20 (29)	ICF Process/Timing Missing Endpoint Assessments	I02.04: Informed consent not signed and/or dated by appropriate site staff P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492241	2020-09-23 (1) 2020-10-21 (29)	Study Procedures/Assessments Missing Endpoint Assessments Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects) P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492243	2020-10-21 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492245	2020-10-21 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3492250	2021-01-21 (120)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492253	2021-01-19 (118)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492255	2020-10-24 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3492259	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3492260	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3492264	2020-10-23 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492265	2020-11-30 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3492267	2020-10-27 (30)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3492272	2021-01-15 (109)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492273	2021-01-19 (112)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492275	2021-01-21 (114)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492276	2021-01-12 (105) 2021-03-12 (164)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3492279	2021-01-19 (112) 2021-02-03 (127)	ICF Process/Timing ICF Process/Timing	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject
US3492284	2021-01-13 (104) 2021-01-15 (106)	ICF Process/Timing ICF Process/Timing	I02.02: Wrong informed consent version signed I02.02: Wrong informed consent version signed
US3492286	2021-01-15 (106)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492287	2021-01-13 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3492291	2021-01-12 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492292	2021-01-19 (106) 2021-03-12 (158)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3492294	2021-01-15 (100)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492297	2021-01-12 (93)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3492300	2021-01-13 (93)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3502002	2020-12-03 (106)	Data Privacy	I01.01: Breach of subject confidentiality
US3502009	2020-12-03 (105)	Data Privacy	I01.01: Breach of subject confidentiality
US3502013	2020-12-03 (102)	Data Privacy	I01.01: Breach of subject confidentiality
US3502033	2020-12-03 (100)	Data Privacy	I01.01: Breach of subject confidentiality
US3502040	2020-12-03 (99)	Data Privacy	I01.01: Breach of subject confidentiality
US3502058	2020-09-26 (30)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502102	2020-09-21 (18)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3502104	2020-09-19 (16)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3502116	2020-09-08 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3502135	2020-09-20 (11)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-07 (28)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3502137	2020-10-08 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3502148	2021-03-02 (173)	Study Procedures/Assessments	P08: Lab samples not shipped, collected and/or processed per protocol or lab manual (expired tubes, ambient shipment, incorrect lab kit used)
US3502155	2020-11-16 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502164	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3502166	2020-12-03 (78)	Data Privacy	I01.01: Breach of subject confidentiality
US3502169	2020-12-03 (77)	Data Privacy	I01.01: Breach of subject confidentiality
US3502172	2020-12-03 (73)	Data Privacy	I01.01: Breach of subject confidentiality
US3502180	2020-10-20 (26)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-27 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3502186	2020-12-03 (60)	Data Privacy	I01.01: Breach of subject confidentiality
US3502193	2020-12-03 (59)	Data Privacy	I01.01: Breach of subject confidentiality
US3502196	2020-12-03 (56)	Data Privacy	I01.01: Breach of subject confidentiality
US3502206	2020-11-16 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3502206	2020-12-03 (51)	Data Privacy	I01.01: Breach of subject confidentiality
US3502212	2020-10-19 (1)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3502217	2020-12-03 (42)	Data Privacy	I01.01: Breach of subject confidentiality
US3502218	2020-10-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3512013	2021-01-15 (163)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3512023	2020-08-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512024	2020-08-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512024	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512025	2020-08-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512026	2020-08-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512030	2020-08-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512030	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512031	2020-08-08 (1)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-11 (4)	Study Treatment Admin/Dispense	P05.04: Use of study treatment at V1 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3512035	2020-09-16 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512045	2020-08-12 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3512070	2020-09-15 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512072	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512076	2021-01-08 (148)	Missing Endpoint Assessments Study Procedures/Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3512077	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512086	2020-09-13 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512089	2020-12-29 (137)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512091	2021-01-05 (144)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512099	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512117	2020-08-21 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-12-28 (130)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512118	2020-08-31 (11)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3512132	2020-12-29 (130)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512134	2020-11-13 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512149	2020-11-25 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-19 (178)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512174	2020-11-13 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512177	2020-10-04 (37)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3512222	2021-01-07 (126)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512224	2020-11-03 (61)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512228	2021-03-24 (201)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3512237	2020-12-07 (94)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3512239	2020-09-21 (13)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3512246	2020-11-20 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3512270	2020-10-22 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512271	2021-01-08 (115)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3512276	2020-09-08 (-10)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3512287	2020-12-07 (69)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3512288	2021-03-21 (172)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-25 (176)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3512289	2020-11-20 (45)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3512297	2020-10-21 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3512301	2020-10-20 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3512301	2020-11-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3512302	2020-10-30 (10)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3512312	2020-12-07 (46)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3522001	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522009	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522014	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522016	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-13 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522017	2020-08-05 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522023	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522029	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522030	2020-08-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522031	2020-09-04 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-22 (48)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522032	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-03 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522035	2021-01-11 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522038	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522043	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522044	2020-09-11 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522047	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522064	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522072	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522075	2021-01-27 (170)	ICF Process/Timing	I02.01: Signed informed consent not available on site

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522082	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522091	2020-09-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522103	2020-08-12 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522107	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522111	2020-09-15 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522114	2020-09-09 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-15 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522133	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522137	2020-08-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522152	2021-03-03 (199)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522154	2021-03-03 (199)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522157	2020-10-06 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522171	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522173	2020-09-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522182	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522182	2020-09-11 (25)	Missing Endpoint Assessments Visit Scheduling	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P10.01: Onsite Visits not performed or out of window
US3522191	2020-08-18 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-16 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522193	2020-08-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522206	2020-08-19 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522220	2020-08-19 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522223	2020-09-21 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522249	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522252	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522253	2021-02-09 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3522258	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522262	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522263	2021-03-04 (196)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522265	2020-10-27 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522273	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522275	2020-09-23 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522286	2020-10-23 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522303	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522306	2020-09-22 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522313	2020-09-21 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-27 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522321	2020-09-21 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522328	2020-10-01 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522331	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522339	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522339	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522351	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-29 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522356	2020-09-23 (30)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522358	2020-08-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522362	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522367	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522368	2020-08-26 (-5)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522368	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522385	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522404	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522410	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3522416	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522426	2020-09-29 (33)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522452	2020-10-02 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522465	2020-09-24 (25)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522470	2020-10-01 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522484	2020-10-23 (53)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3522486	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522489	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522510	2020-11-09 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522528	2020-09-02 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-29 (28)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3522537	2020-12-18 (108)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522542	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3522548	2020-09-29 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3522549	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522556	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-14 (73)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-02 (181)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3522572	2020-11-12 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522594	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3522597	2020-11-13 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522610	2020-10-23 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3522641	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3522661	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522663	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522664	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522665	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3522665	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-20 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3522666	2020-09-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3522684	2020-11-17 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3532001	2021-01-11 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532002	2021-01-11 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532003	2021-01-11 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532005	2021-01-22 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532011	2020-11-17 (98)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-22 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532012	2021-01-20 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532013	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532013	2021-01-27 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532014	2021-01-21 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532017	2021-01-22 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532019	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532022	2021-01-22 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532025	2021-01-12 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532027	2021-01-12 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532029	2021-01-28 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532030	2021-01-07 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532035	2021-01-12 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532036	2021-01-13 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532037	2021-01-06 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532042	2021-01-22 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532043	2021-01-21 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532044	2021-01-11 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532045	2021-01-25 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532048	2021-01-07 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532055	2021-01-20 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532056	2021-01-26 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532058	2021-01-14 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532059	2021-01-07 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532062	2021-01-13 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532064	2021-01-22 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532067	2021-01-13 (149) 2021-03-19 (214)	ICF Process/Timing Missing Endpoint Assessments	I02.02: Wrong informed consent version signed P07.01: Blood sample not taken when required per protocol
US3532072	2021-01-20 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532073	2021-01-13 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532077	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532079	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532083	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532084	2021-01-20 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532085	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532086	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532089	2021-01-14 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532092	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532093	2021-01-13 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532094	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532096	2021-01-11 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532097	2021-01-20 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532099	2021-01-22 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532100	2021-01-27 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532108	2020-10-01 (42)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532108	2021-01-07 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532109	2020-08-21 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-21 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532112	2021-01-13 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532113	2021-01-20 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532115	2021-01-08 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532118	2021-01-07 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532121	2021-01-20 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532122	2021-01-12 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532124	2020-09-22 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-21 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532125	2021-01-21 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532127	2021-01-21 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532128	2021-01-20 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532132	2021-01-25 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532135	2021-02-11 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532136	2021-01-26 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532140	2020-08-28 (4)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-01-06 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532143	2021-01-06 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532145	2021-01-20 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532146	2021-01-26 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532148	2021-01-22 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532149	2021-01-20 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532152	2021-01-28 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532154	2021-01-13 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532159	2021-01-20 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532160	2021-01-06 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532162	2021-01-25 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532164	2021-01-06 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532166	2021-01-26 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532167	2021-01-12 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532168	2021-01-12 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532172	2021-01-07 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532177	2021-01-08 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532179	2021-01-08 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532181	2021-01-11 (134) 2021-03-08 (190)	ICF Process/Timing Visit Scheduling	I02.02: Wrong informed consent version signed P10.01: Onsite Visits not performed or out of window
US3532182	2021-01-27 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532186	2021-01-26 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532188	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-06 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532192	2020-11-11 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-25 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532193	2021-01-25 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532197	2021-01-26 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532198	2021-01-26 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532199	2021-01-20 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532202	2020-12-28 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3532204	2021-01-26 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532205	2021-01-25 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532208	2021-01-07 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532213	2021-01-21 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532214	2021-01-20 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532216	2021-01-25 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532219	2021-01-22 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532220	2021-01-22 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532224	2021-01-25 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532225	2021-01-21 (142)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532230	2021-01-11 (131)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532231	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532233	2021-01-20 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532235	2021-01-28 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532236	2021-01-06 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532240	2021-01-08 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532241	2021-01-12 (132)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532242	2021-01-20 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532243	2021-01-07 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532245	2021-01-21 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532247	2020-10-07 (30)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2021-01-12 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532248	2021-01-12 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532252	2021-01-07 (122)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532257	2020-12-03 (87)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-26 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532259	2020-11-04 (57)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-09 (62)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-11 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532261	2021-01-07 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532264	2021-01-11 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532267	2021-01-27 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3532268	2021-01-26 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532270	2021-01-07 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532271	2021-02-02 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532277	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-27 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532278	2021-01-12 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532279	2021-02-05 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3532281	2021-01-12 (125)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3542008	2020-09-11 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542013	2020-08-17 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542018	2021-01-22 (158)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3542027	2020-09-07 (19)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542029	2020-12-07 (110)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-22 (215)	Data Privacy	I01.01: Breach of subject confidentiality
US3542036	2020-09-23 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542041	2021-01-29 (162)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2021-03-26 (218)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3542048	2020-09-14 (22)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3542049	2020-10-05 (43)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3542050	2020-08-25 (2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-16 (54)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542054	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542058	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542062	2020-08-30 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3542068	2020-09-02 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542077	2020-10-12 (46)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542087	2021-01-26 (152)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3542095	2020-10-02 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542101	2020-09-25 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542105	2020-09-29 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542116	2020-09-22 (22)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542135	2021-03-22 (202)	Data Privacy	I01.01: Breach of subject confidentiality
US3542136	2020-10-08 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3542146	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-03 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542149	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542150	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542157	2020-10-13 (40)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542161	2020-09-29 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542169	2020-10-06 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542170	2020-10-08 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542180	2020-09-08 (1)	Study Procedures/Assessments	P08.04: Contraceptive method not used according to protocol (through 3 months following the second dose (Day 29)
US3542185	2020-10-13 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542186	2020-09-18 (10)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-13 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3542203	2020-10-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3542206	2020-10-20 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542222	2021-03-09 (177)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542224	2020-09-14 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-02 (19)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542234	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3542245	2020-10-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-31 (107)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3542247	2020-09-17 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-16 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-15 (121)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-02-16 (153)	Withdrawal/Term Criteria	P11.01: Anytime withdrawal criteria are met but subject was not withdrawn

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542253	2020-10-23 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3542274	2020-10-28 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3542276	2020-09-29 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542280	2020-10-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542283	2020-11-03 (42)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3542286	2020-10-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542289	2020-09-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-05 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3542300	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542309	2020-11-13 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3542310	2020-10-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3542319	2020-11-04 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3542329	2020-10-19 (12)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-03 (57)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3542332	2020-11-12 (35)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3542335	2020-10-27 (16)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3542343	2020-11-18 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-09 (57)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-05 (84)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3542347	2020-12-25 (71)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-01-21 (98)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3542358	2020-12-04 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3552004	2020-10-29 (80)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552011	2020-08-12 (1)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552022	2020-08-13 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-02 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3552024	2020-08-18 (6)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-09-14 (33)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3552028	2020-08-13 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3552050	2020-08-25 (9)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552062	2020-09-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552082	2020-08-25 (7)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552090	2020-08-21 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3552097	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3552106	2020-10-06 (48)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552126	2020-09-14 (25)	Study Procedures/Assessments	P08.08: Blood sample drawn outside allowed time window on dosing days (blood samples not collected prior to the first dose of IP)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552155	2020-08-25 (1)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552156	2020-08-25 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552181	2020-08-31 (6)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-10-09 (45)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552189	2020-10-20 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-12-10 (107)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-03-24 (211)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3552191	2020-10-02 (38)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552221	2020-09-21 (25)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552248	2021-02-25 (179)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552249	2020-11-20 (82)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3552258	2020-09-06 (7)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552265	2020-09-28 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3552301	2020-09-02 (1)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552317	2020-09-04 (2)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-02-01 (152)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3552326	2020-10-05 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3552330	2020-09-24 (21)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552353	2020-10-04 (28)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552355	2020-09-10 (3)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552359	2020-10-29 (52)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552434	2020-09-21 (7)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552448	2020-10-12 (27)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3552450	2021-01-14 (120)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3552495	2020-10-26 (31)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3552499	2021-03-04 (160)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3552508	2020-10-01 (-1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-04 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-06 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3552524	2020-10-22 (14)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3552531	2020-12-15 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562002	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3562003	2020-08-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-08 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3562017	2020-10-02 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3562030	2020-09-11 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3562033	2020-08-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3562056	2020-09-18 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3562057	2020-10-07 (49)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562061	2021-01-13 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3562099	2020-09-04 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-25 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3562115	2021-01-05 (125)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3562116	2020-11-09 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562159	2021-01-06 (117)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3562164	2020-11-05 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562169	2020-10-09 (25)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-04 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562222	2020-11-13 (36)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3562234	2020-10-19	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3572002	2020-08-19 (3)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3572008	2020-09-22 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572011	2020-10-28 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572014	2020-08-18 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572018	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572020	2020-08-20 (2)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-09-24 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572021	2020-10-15 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572026	2020-09-22 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-23 (36)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3572030	2020-09-02 (15)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-11-03 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-04 (78)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572030	2020-12-18 (122)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2021-02-08 (174)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3572034	2020-09-28 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572043	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-29 (41)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572048	2020-08-20 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572051	2020-09-28 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572057	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572057	2020-09-22 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572061	2020-12-28 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572066	2020-11-04 (73)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3572072	2020-08-23 (-1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-11-26 (95)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-30 (99)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3572084	2020-08-24 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572085	2020-09-23 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572097	2020-09-24 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572103	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3572117	2020-08-26 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572121	2020-08-26 (-16)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3572123	2020-08-27 (1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3572128	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-19 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3572129	2020-09-17 (21)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-10-02 (36)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572129	2020-11-04 (69)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-29 (124)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-25 (182)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572131	2020-11-06 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572137	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3572138	2020-09-28 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572149	2020-08-31 (-10)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3572152	2020-09-29 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572154	2020-09-29 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572158	2020-10-06 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572161	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-02 (155)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572164	2020-09-30 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572172	2020-11-20 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572178	2020-10-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-21 (110)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572182	2020-09-02 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572189	2020-11-04 (62)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572189	2020-11-30 (88)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3572190	2020-10-05 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572194	2020-10-10 (37)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572197	2020-09-05 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572210	2020-09-22 (16)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3572225	2020-10-05 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-17 (101)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572231	2020-10-13 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572232	2020-10-14 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572233	2020-10-07 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572251	2020-09-09 (-1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-11 (93)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572255	2020-12-04 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572263	2020-10-08 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572270	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572271	2020-11-12 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572272	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572285	2020-11-17 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572287	2020-10-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572291	2021-02-18 (158)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3572292	2020-10-16 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572300	2020-09-14 (-2)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3572302	2020-10-15 (31)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-08 (85)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572319	2020-12-09 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572321	2020-09-16 (-5)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-17 (-4)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-22 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-20 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3572325	2020-11-30 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572326	2020-09-18 (-10)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3572330	2020-11-01 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572333	2020-09-21 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572334	2020-11-24 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572335	2020-12-18 (88)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3572345	2020-12-29 (98)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572355	2020-09-29 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-02 (35)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-11-18 (51)	Accidental Unblinding	P12.01: Inadvertent unblinding of site personnel
US3572356	2020-12-11 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572359	2020-12-21 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572366	2020-11-13 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3572368	2020-10-06 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-07 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3572372	2020-10-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3572376	2020-12-10 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3572382	2020-10-06 (-3)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3572390	2020-12-26 (76)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3572391	2020-11-11 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3572406	2020-11-25 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3582021	2020-09-16 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3582027	2020-08-21 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3582036	2020-09-14 (22)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3582049	2020-09-21 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3582056	2020-12-28 (124)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3582072	2020-08-28 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-18 (22)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-20 (115)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3582081	2021-01-19 (141)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3582099	2020-10-06 (34)	Concomitant Medication Missing Endpoint Assessments	P09.01: Prohibited concomitant medication or vaccine received by subject P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3582110	2020-09-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3582118	2020-10-17 (40)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3582121	2020-09-24 (16)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3582134	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3582148	2020-10-26 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3582149	2020-10-19 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3582153	2021-02-09 (146)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3582176	2020-10-06 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-02 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-30 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3592010	2021-01-26 (175)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592016	2021-01-28 (177)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592019	2020-08-14 (10)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3592024	2020-09-05 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-15 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592025	2020-09-03 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-09-22 (48)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3592026	2021-01-26 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592028	2020-08-25 (20)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-06 (62)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3592031	2021-01-18 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592032	2020-08-07 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-05 (31)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3592034	2020-09-03 (29)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
	2021-01-26 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-02-23 (202)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3592038	2020-08-07 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-22 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-17 (223)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3592040	2020-09-04 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592040	2021-01-19 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592043	2021-01-19 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592050	2021-01-18 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592051	2021-01-21 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592052	2020-08-07 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-22 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592056	2021-01-19 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592057	2021-01-19 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592058	2021-01-25 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592062	2020-09-11 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3592077	2021-01-27 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592088	2021-01-28 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592089	2021-01-25 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592091	2020-08-16 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-21 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592102	2020-09-13 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-25 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592104	2021-01-21 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592106	2020-09-07 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3592111	2021-01-18 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592112	2021-01-27 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592116	2021-01-19 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592120	2021-01-26 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592125	2021-01-25 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592128	2021-01-20 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592133	2021-01-28 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592134	2020-09-20 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3592141	2021-01-27 (168)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3592142	2020-09-11 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592143	2021-01-20 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592144	2020-08-14 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-14 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-26 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592148	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592151	2021-01-18 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592152	2020-09-12 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592153	2020-09-16 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3592160	2020-09-15 (33)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-16 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-28 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592162	2020-12-08 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-01-27 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592165	2021-01-22 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592173	2021-01-22 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592174	2021-01-27 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592179	2021-01-22 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592184	2021-01-28 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592190	2021-01-25 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592193	2021-01-20 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592197	2020-10-14 (60)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3592205	2020-09-16 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3592208	2020-08-15 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3592211	2021-01-27 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592214	2020-10-07 (52)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-19 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592215	2021-01-22 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592216	2021-01-21 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592220	2021-01-18 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3592226	2021-01-15 (151)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3592227	2021-01-22 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592239	2021-01-21 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592241	2021-01-20 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592242	2021-01-20 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3592245	2021-01-21 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3602004	2021-01-03 (124)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3602005	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-03 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3602007	2020-12-14 (104)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602017	2020-09-24 (21)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3602023	2020-09-10 (1)	ICF Process/Timing	I02.01: Signed informed consent not available on site
	2020-10-09 (30)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3602037	2020-09-14	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-12-18	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3602057	2020-10-05 (8)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3602059	2020-10-16 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3602061	2020-10-16 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3602064	2020-10-16 (29)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602067	2020-10-20 (30)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3602070	2020-10-31 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3602071	2020-10-25 (35)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3602078	2020-11-01 (41)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3602079	2020-10-10 (19)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-20 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3602093	2020-10-27 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-01 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-14 (83)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3602094	2020-09-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3602099	2020-10-23 (30)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3602107	2021-03-04 (161)	Data Privacy	I01.01: Breach of subject confidentiality
US3602108	2020-09-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-27 (33)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3602157	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3612008	2020-09-01 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3612020	2020-11-10 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3612045	2020-09-18 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3612047	2020-10-05 (18)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3612070	2020-10-06 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3612072	2020-10-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3612079	2020-11-15 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622005	2020-09-04 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622010	2020-12-15 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622013	2020-08-24 (13)	ICF Process/Timing	I02.01: Signed informed consent not available on site
US3622030	2020-10-15 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622059	2020-10-16 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3622064	2020-10-28 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622078	2020-10-29 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622082	2020-09-22 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-03 (162)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3622083	2020-11-03 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622090	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622133	2020-09-30 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622151	2020-10-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622153	2020-10-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622156	2020-11-14 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622160	2020-09-05 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3622163	2020-10-02 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622173	2020-12-03 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622192	2020-09-16 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3622197	2020-10-14 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622213	2020-09-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-18 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622217	2020-09-22 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-23 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3622221	2020-09-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-19 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-24 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622229	2020-12-15 (82)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3622230	2020-09-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622230	2020-10-22 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622252	2020-12-04 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622254	2020-11-01 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-02 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3622260	2020-11-12 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3622269	2020-11-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3622278	2020-10-19 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-30 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3622281	2020-10-24 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-17 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-28 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3632050	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3632061	2020-10-30 (52)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-01 (54)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3632098	2020-10-15 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632101	2020-11-24 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3632119	2020-10-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-02 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-02 (56)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-12-07 (61)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-10 (64)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-14 (68)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-15 (69)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3632133	2021-01-25 (103)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3632135	2020-10-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3632146	2020-11-03 (15)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632157	2020-12-17 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3632158	2020-10-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3642005	2020-08-22 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (140)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642008	2021-01-08 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642010	2021-01-08 (138)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642014	2020-08-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642016	2020-08-26 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642017	2020-12-30 (127)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642019	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642020	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642021	2021-01-08 (136)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642022	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642026	2020-08-26 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642027	2020-08-26 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-18 (53)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642028	2021-01-08 (135)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642030	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642032	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642033	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642034	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642036	2020-08-27 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642037	2021-01-08 (134)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642041	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642044	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642045	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642047	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642048	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642055	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642056	2021-01-08 (133)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642059	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642061	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642062	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642063	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642064	2020-08-31 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642067	2021-01-08 (131)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642069	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642073	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642075	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642077	2020-09-01 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-01-08 (130)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642080	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642082	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642084	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642088	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642089	2020-09-01 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-08 (129)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642090	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642092	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642095	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642096	2020-09-02 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-08 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642098	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642099	2021-01-08 (127)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3642105	2020-10-06 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3642112	2020-09-04 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3642114	2020-10-02 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642123	2020-10-02 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-19 (45)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3642133	2020-09-05 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-19 (137)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3642140	2020-09-07 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-05 (59)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642172	2020-09-10 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3642176	2020-09-11 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3642188	2020-10-15 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642188	2020-11-06 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642199	2020-10-11 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3642201	2020-11-14 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642207	2020-09-13 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3642208	2020-11-08 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642215	2021-02-13 (152)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642221	2020-09-14 (-1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3642225	2020-09-19 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642225	2020-10-21 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3642230	2020-11-10 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642232	2020-10-16 (30)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3642234	2020-09-17 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3642239	2020-11-20 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642240	2020-09-17 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3642284	2020-09-27 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642284	2021-01-04 (99)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642294	2020-10-30 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3642296	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-25 (85)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642297	2020-10-30 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-12-04 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3642301	2020-10-02 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3642315	2020-11-12 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3642327	2020-12-29 (75)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3642332	2020-11-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3642344	2020-10-22 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3652023	2020-10-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3652030	2020-10-02 (4)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3652031	2020-12-04 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3652038	2020-10-30 (36)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-12-22 (89)	Inv Randomization/Unblinding	I07.01: Unblinding of subject by sponsor/CRO personnel not done per study procedures

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3652048	2020-10-05 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-11 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3652050	2020-09-30 (-7)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3652052	2020-10-13 (-3)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-19 (4)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3652060	2020-12-23 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3662005	2020-09-27 (24)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662024	2020-09-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662028	2020-11-17 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3662029	2020-09-07 (-1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2020-10-09 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3662036	2020-09-01 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3662040	2020-09-11 (10)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-10 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3662050	2020-10-05 (32)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-10-20 (47)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662075	2020-10-09 (30)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-25 (77)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662081	2020-10-08 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3662084	2020-09-24 (14)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662091	2020-09-28 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662092	2020-10-11 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3662099	2020-09-30 (16)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3662107	2020-10-27 (42)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662112	2020-11-09 (54)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3662115	2020-10-08 (22)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-26 (40)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3662121	2020-10-08 (18)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-18 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3662122	2020-10-06 (16)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2020-10-18 (28)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-10-28 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3662135	2021-01-25 (124)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3662137	2020-10-09 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-13 (50)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3662139	2020-09-25 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3662145	2021-01-29 (123)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3662182	2020-11-02 (12)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3672007	2021-01-15 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672008	2021-01-21 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672009	2021-02-01 (180)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672010	2021-02-03 (182)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672011	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-19 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672016	2021-01-25 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672017	2021-01-15 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672019	2021-02-10 (188)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672020	2021-02-22 (200)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672022	2021-01-26 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672024	2021-01-29 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672030	2021-02-01 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672031	2021-02-03 (178)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672034	2021-01-31 (175)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672035	2020-10-07 (59)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672036	2021-01-15 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672039	2021-01-25 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672041	2021-01-25 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672042	2021-01-15 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672045	2021-01-19 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672046	2021-01-21 (165)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672048	2021-01-26 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672049	2021-01-21 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672051	2021-02-02 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672052	2021-01-31 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672055	2021-01-15 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672056	2021-01-19 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672057	2021-01-19 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672059	2021-01-25 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672063	2021-01-25 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672067	2021-01-19 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672069	2021-01-22 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672072	2021-01-18 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672074	2021-01-25 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672075	2021-02-02 (175)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672077	2020-10-07 (57)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-11-30 (111)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-01 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672080	2021-01-25 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672085	2021-01-25 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672087	2021-01-29 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672088	2020-11-30 (110)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-22 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672089	2021-01-29 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672092	2020-09-09 (28)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-29 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672093	2021-02-01 (173)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672094	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672096	2021-01-21 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672098	2021-01-19 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672100	2021-01-21 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672105	2021-01-21 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672106	2021-01-25 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672109	2021-01-20 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672112	2021-01-22 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672114	2021-01-20 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672115	2021-02-05 (176)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672118	2021-01-22 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672119	2021-01-22 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672120	2021-01-20 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-02 (201)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672122	2021-01-21 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672123	2021-01-19 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672125	2020-10-21 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-07 (116)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-27 (167)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672129	2021-01-25 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672130	2021-01-21 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672131	2021-01-25 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672134	2021-01-15 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672135	2021-01-15 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672140	2021-01-19 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672142	2021-01-20 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672145	2021-02-02 (170)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672147	2021-01-19 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672148	2021-02-03 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672149	2021-01-27 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672152	2021-01-26 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672153	2021-02-04 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672154	2021-01-22 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672158	2021-01-25 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672159	2021-01-26 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672162	2021-01-22 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672163	2020-09-14 (28)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-19 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672168	2021-01-27 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672171	2021-01-25 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672174	2021-01-21 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672176	2021-01-20 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672177	2021-02-15 (182)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672178	2021-01-22 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672183	2021-01-20 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed I02.04: Informed consent not signed and/or dated by appropriate site staff
US3672184	2021-02-03 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672186	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672189	2021-01-26 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672190	2020-12-07 (111)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-22 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672193	2021-01-19 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672195	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672197	2021-01-20 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672200	2021-01-26 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672202	2021-01-28 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672202	2021-01-28 (163)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3672204	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672205	2021-01-29 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672208	2021-01-21 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672209	2021-01-18 (153)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672217	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672218	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672220	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672221	2021-01-21 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672224	2021-01-26 (160)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672226	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672227	2021-01-24 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672229	2021-01-28 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672235	2021-01-27 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672237	2021-01-22 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672240	2020-12-07 (110)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3672241	2021-01-22 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672242	2021-01-21 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672245	2021-01-27 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672246	2021-01-24 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672247	2021-01-21 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672249	2021-01-20 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672251	2020-09-23 (34)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-31 (164)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672252	2021-01-21 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672253	2021-01-28 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672255	2021-02-02 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672258	2021-01-25 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672259	2021-01-20 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672261	2020-09-22 (33)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-01-22 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672264	2021-01-24 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672266	2021-01-28 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672267	2021-01-20 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672271	2021-01-18 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672275	2021-01-27 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672276	2021-01-24 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672280	2021-01-22 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672281	2021-01-25 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672284	2021-02-02 (163)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672285	2021-01-26 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672286	2021-01-25 (155)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672287	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3672289	2020-11-05 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-01 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672293	2021-01-20 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672294	2021-01-21 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672295	2021-01-20 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672296	2021-02-01 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672298	2020-09-28 (35)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3672302	2020-10-01 (38)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-01-22 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672303	2020-11-03 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672303	2021-01-28 (157)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672304	2021-01-29 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672309	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672314	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-26 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672315	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672316	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672317	2021-01-22 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672318	2020-09-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-22 (150)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672319	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672322	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672325	2021-01-19 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672327	2021-01-21 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672330	2021-01-18 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672331	2021-01-18 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672334	2021-02-02 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672336	2021-01-14 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672338	2021-01-21 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672340	2021-01-24 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672341	2021-01-22 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672344	2021-01-21 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672346	2020-10-23 (58)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3672349	2021-01-21 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672351	2021-01-21 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672352	2021-01-24 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672353	2021-01-22 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672354	2021-01-29 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672355	2021-02-03 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672356	2021-01-21 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672359	2021-02-01 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672360	2021-01-18 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672365	2021-01-20 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672366	2021-01-27 (154)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672369	2020-10-29 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-29 (155)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-05 (190)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672370	2021-02-01 (158)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672377	2020-09-30 (34)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-02-04 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672378	2020-12-07 (102)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-25 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672379	2021-01-22 (148)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3672382	2020-10-20 (54)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3672384	2021-01-24 (147)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672386	2021-01-20 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672388	2021-01-21 (144)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672389	2020-11-04 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-29 (152)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672390	2021-01-20 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672395	2021-01-24 (146)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672396	2021-01-20 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672398	2020-11-06 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-19 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672400	2021-01-20 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672401	2020-09-02 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2021-01-24 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672403	2020-11-05 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-28 (148)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672404	2021-01-20 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672406	2021-01-20 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3672408	2020-11-06 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3672409	2021-01-21 (140)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3672411	2021-01-25 (144)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3682005	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3682017	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-30 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-13 (80)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3682020	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3682024	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3682026	2020-08-27 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3682036	2020-10-02 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3682041	2020-09-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3682069	2020-10-05 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682074	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3682084	2020-09-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3682098	2020-10-12 (29)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3682100	2020-11-16 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3682104	2020-10-19 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682134	2020-09-16 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3682135	2020-09-17 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3682146	2020-10-15 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682154	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682155	2020-10-19 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3682166	2020-10-30 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3682168	2020-10-19 (25)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3692009	2020-08-27 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692027	2020-08-31 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692038	2020-09-01 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692044	2020-11-06 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3692053	2020-09-03 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692054	2020-09-14	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3692084	2020-09-08 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692095	2020-09-10 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692100	2020-09-10 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692102	2020-09-10 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692103	2020-09-10 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692108	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3692113	2020-09-11 (-3)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-09-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3692123	2020-09-14 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692124	2020-09-14 (-1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692148	2020-09-21 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692150	2020-09-22 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692151	2020-09-22 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2021-03-01 (159)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3692157	2020-09-25 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3692164	2020-10-02 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692168	2020-10-15 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692194	2020-10-11 (-4)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3692202	2020-10-20 (-2)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-10-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3702003	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3702006	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3702010	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-02 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3702010	2020-10-02 (29)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3702023	2020-10-23 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3702045	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3702046	2020-10-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3702052	2020-10-30 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3702090	2020-11-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3702093	2020-10-22 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712006	2020-09-08 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
	2021-02-22 (168)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712007	2021-02-05 (151)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712024	2020-10-13 (34)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3712028	2021-01-14 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712031	2020-09-08 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3712032	2020-10-08 (29)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-02 (54)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2021-02-16 (160)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-22 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712034	2021-02-13 (158)	Study Treatment Admin/Dispense	P05.13: Subject received more than 2 doses of mRNA-1273 P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3712035	2020-10-22 (43)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-17 (99)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-02-22 (166)	ICF Process/Timing	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject
US3712037	2020-09-09 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3712040	2020-10-20 (41)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3712041	2020-10-06 (27)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3712048	2021-02-03 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712051	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712053	2021-01-29 (137)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712057	2021-02-02 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712058	2020-10-16 (32)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2020-11-13 (60)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2020-11-20 (67)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-12-22 (99)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-02-02 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712061	2021-02-08 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712064	2021-01-29 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712065	2020-09-16 (-2)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712068	2021-02-04 (143)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712085	2020-10-15 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-01 (138)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712090	2021-01-29 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712091	2021-01-27 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712093	2021-02-05 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712101	2020-11-23 (64)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
	2021-01-26 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712102	2020-11-23 (64)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3712104	2020-12-30 (101)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3712109	2021-01-14 (119)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712110	2021-02-04 (136)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712112	2020-10-23 (31)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3712118	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-21 (30)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-08 (109)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712119	2020-10-21 (30)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-29 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712120	2021-01-14 (112)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712127	2021-01-28 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712128	2021-01-28 (127)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712130	2021-01-27 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712138	2021-01-29 (128)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712145	2021-01-14 (115)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712146	2021-02-02 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712151	2021-03-05 (162)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712154	2021-02-04 (135)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712155	2021-02-15 (141)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712157	2021-01-27 (126)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712165	2021-02-04 (133)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712168	2020-12-11 (78)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3712170	2021-02-19 (149)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712171	2020-10-01 (7)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712171	2020-10-26 (32)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3712173	2021-02-04 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712176	2020-10-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3712177	2021-02-23 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712180	2021-01-27 (101)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712182	2021-01-28 (106)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712189	2021-01-26 (103)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712193	2020-11-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3712198	2021-01-07 (84)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3712199	2020-10-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712199	2020-11-23 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3712209	2020-11-12 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3712213	2020-10-14 (-5)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3712217	2021-01-11 (81)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712218	2020-10-23 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3712219	2021-02-19 (121)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712231	2021-01-28 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712240	2021-02-05 (108)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712245	2021-02-02 (106)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712255	2021-01-28 (100)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712258	2021-02-05 (106)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712262	2021-02-02 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3712264	2021-01-28 (102)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712281	2021-01-08 (78)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-01-28 (98)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-09 (110)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712285	2021-01-29 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712294	2021-02-04 (105)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712298	2021-02-02 (103)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712299	2021-01-08 (78)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3712302	2020-12-30 (69)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3712309	2021-01-29 (99)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3722003	2020-07-31 (-2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722005	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722007	2020-07-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722008	2020-07-31 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722009	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722010	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722011	2020-08-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722015	2020-08-01 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722016	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722016	2020-09-01 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722018	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722020	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722022	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722029	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722030	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722036	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722041	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722047	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722049	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722050	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722055	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722056	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722059	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722059	2020-10-07 (66)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3722063	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722065	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722069	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-02 (61)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3722072	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-12 (41)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722089	2020-09-02 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722091	2020-09-02 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722119	2020-08-06 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722125	2020-12-08 (125)	Missing Endpoint Assessments	P07.08: Subjects confirmed of COVID-19 did not collect saliva samples during the 28 day period following the diagnosis of SARS-CoV-2 infection
	2020-12-11 (128)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3722126	2021-01-18 (166)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3722132	2020-08-10 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722147	2020-08-07 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3722165	2020-09-04 (26)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3722173	2020-09-09 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722197	2020-09-04 (25)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite visits not performed or out of window
US3722210	2020-09-18 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3722236	2020-09-30 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3722249	2020-09-15 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722261	2021-01-28 (168)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722270	2020-09-15 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722282	2020-09-23 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3722291	2020-08-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3722309	2020-09-24 (37)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3722311	2020-08-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-15 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722329	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722371	2020-09-30 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722371	2021-01-11 (141)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722391	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722393	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-03 (70)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3722394	2020-08-26 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3722395	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3722403	2020-09-27 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3722406	2020-11-12 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3722406	2021-01-04 (130)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3722418	2020-09-12 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2021-02-02 (144)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3722423	2020-09-22 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-18 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-28 (42)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite visits not performed or out of window
US3722438	2020-10-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-03 (107)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3732005	2020-09-01 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732005	2020-09-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732018	2021-03-05 (212)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3732022	2020-08-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732027	2021-03-18 (224)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732037	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-17 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732048	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732057	2020-09-09 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-16 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732071	2020-08-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732072	2020-08-14 (1)	Study Treatment Randomization	P04.03: Subject enrolled/dosed at two sites
US3732079	2020-09-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732084	2020-08-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732099	2020-09-16 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3732100	2020-09-23 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732103	2020-09-16 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732115	2020-09-17 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732123	2020-08-24 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732128	2020-10-30 (71)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3732161	2020-09-11 (18)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732162	2020-11-05 (73)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3732166	2020-09-22 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732168	2020-08-25 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown
	2020-09-22 (29)	Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown
	2020-12-18 (116)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732186	2020-09-23 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3732192	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732205	2020-09-18 (23)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-03 (69)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3732221	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732222	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732239	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732272	2020-12-28 (117)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732275	2020-10-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-12-10 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732278	2020-12-15 (103)	Concomitant Medication Study Treatment Admin/Dispense	P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3732279	2020-10-11 (38)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732284	2020-09-04 (1) 2020-10-02 (29)	Study Treatment Admin/Dispense Missing Endpoint Assessments Study Treatment Admin/Dispense	P05.01: Route of administration is wrong or unknown P07.10: Subject Diary not completed 30 min post dosing P05.01: Route of administration is wrong or unknown
US3732286	2020-09-04 (1) 2020-10-14 (41) 2020-12-01 (89)	Study Procedures/Assessments Study Procedures/Assessments Missing Endpoint Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects) P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs P07.07: Saliva sample not collected when required per protocol
US3732295	2020-12-07 (90)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732300	2020-10-19 (41)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732300	2020-10-21 (43)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-11-30 (83)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3732302	2020-10-14 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732305	2020-10-19 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732309	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-01 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732318	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732321	2020-09-18 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732322	2020-11-04 (55)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732324	2020-10-19 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732325	2020-11-16 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732327	2020-09-21 (8)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-19 (36)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-18 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3732330	2020-10-14 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3732333	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732338	2020-09-15 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-18 (65)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3732344	2020-10-27 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732347	2020-09-16 (1)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
	2020-10-13 (28)	Study Treatment Admin/Dispense	P05.01: Route of administration was not intramuscularly into the deltoid muscle or route of administration is unknown
US3732364	2020-10-13 (23)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3732366	2020-11-13 (54)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3732393	2020-10-16 (3)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732394	2020-10-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3732399	2020-10-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-31 (74)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3732407	2020-10-23 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742004	2020-08-24 (8)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3742007	2021-02-11 (179)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3742009	2020-08-24 (7) 2021-02-11 (178)	ICF Process/Timing ICF Process/Timing	I02.02: Wrong informed consent version signed I02.02: Wrong informed consent version signed
US3742019	2020-09-04 (17)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3742031	2021-02-11 (175)	ICF Process/Timing	I02.02: Wrong informed consent version signed I02.03: Informed consent not signed and/or dated by subject
US3742034	2020-08-25 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742048	2021-02-11 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3742063	2021-01-14 (144)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742070	2020-12-29 (125)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3742072	2021-02-11 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3742081	2020-08-24 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742082	2020-08-25 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3742111	2020-12-23 (119)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3742115	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3742119	2020-09-28 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-05 (67)	Visit Scheduling	P10.01: Onsite visits not performed or out of window
US3742125	2021-01-11 (131)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742126	2020-09-21 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-11 (169)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3742132	2020-11-18 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742168	2021-01-19 (142)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3742169	2020-11-19 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742254	2020-10-28 (55)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3742326	2020-09-10 (-7)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742332	2020-11-12 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742367	2020-12-26 (104)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3742375	2020-11-23 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742411	2020-09-17 (-14)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3742412	2020-11-05 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3742417	2020-12-18 (92)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3742467	2020-09-22 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3742469	2020-11-04 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-02-22 (153)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3752002	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752004	2020-08-06 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752004	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752006	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752008	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-14 (39)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3752009	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752010	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-04 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3752011	2020-08-06 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752013	2020-08-06 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-08-07 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752020	2020-12-21 (134)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752034	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752035	2020-09-11 (32)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752037	2020-08-11 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3752038	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752048	2020-08-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752052	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752058	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752060	2020-09-17 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-08 (150)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-03-09 (210)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3752062	2020-08-12 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752084	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752110	2020-09-14 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752118	2020-09-23 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-01-01 (138)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752120	2020-12-04 (110)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3752143	2021-01-12 (147)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3752159	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3752172	2020-12-04 (107)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2021-01-27 (161)	Concomitant Medication Study Treatment Admin/Dispense	P09.01: Prohibited concomitant medication or vaccine received by subject P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752173	2020-09-20 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752195	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-29 (162)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3752199	2020-09-17 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3752203	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752224	2020-12-17 (116)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3752245	2020-08-25 (1)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-26 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-06 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3752258	2020-12-16 (113)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752272	2020-12-19 (116)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3752279	2020-08-26 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3752312	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3752364	2020-12-20 (110)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-04 (125)	Inv Randomization/Unblinding	I07.01: Unblinding of subject by sponsor/CRO personnel not done per study procedures
US3752390	2020-11-09 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3752393	2020-09-03 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
	2020-10-07 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3752393	2021-01-27 (147)	Inv Safety Reporting (CRF)	I11.01: SAE not entered in eCRF/reported as per study timelines i.e. within 24 hours of being aware of the event
US3752399	2020-10-02 (29)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3752411	2020-10-01 (28)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3752414	2020-10-06 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-18 (106)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3752420	2020-11-09 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762014	2020-09-22 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3762016	2020-08-21 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3762049	2020-11-18 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762060	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3762062	2020-10-02 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3762081	2020-11-05 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762082	2020-11-05 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762096	2020-11-06 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-25 (120)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3762107	2020-11-04 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762111	2020-11-04 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3762156	2020-11-05 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762180	2020-11-13 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762226	2020-10-21 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762258	2020-11-16 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762268	2020-10-21 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3762276	2020-09-22 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3762297	2020-10-11 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772001	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-08 (97)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3772002	2020-11-12 (101)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-12-09 (128)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3772006	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772011	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3772012	2020-09-08 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772013	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772013	2020-09-08 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772015	2020-08-17 (13)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
		Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements
	2020-12-26 (144)	Inv Record Keeping Source Docs	I10.01: Persistent inadequate source documents after re-education
	2021-01-19 (168)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3772017	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-08 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772021	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772022	2020-08-06 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772022	2020-12-15 (132)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
	2021-03-04 (211)	Study Procedures/Assessments	P08.09: Site did not complete the Day 28 Convalescent visit (scheduled approximately 28 days after the initial Illness Visit)
US3772024	2020-08-05	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-08-06	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Treatment Admin/Dispense	P07.06: Nasopharyngeal swab sample not collected when required per protocol P05.09: Participant received less than 2 doses of IP during the study participation
US3772028	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772029	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772030	2020-08-10 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772030	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772031	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3772033	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772034	2020-08-10 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772037	2020-08-11 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-11-07 (89)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772037	2020-11-21 (103)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3772038	2020-08-11 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772039	2020-08-11 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772041	2020-08-11 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772045	2020-08-11 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772046	2020-08-11 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772054	2020-08-12 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772077	2020-09-16 (31)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-13 (150)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2021-01-14 (151)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3772087	2020-08-19 (2)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772098	2020-08-19 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3772099	2020-08-19 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772100	2020-08-19 (1)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-09-20 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772104	2020-08-20 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772107	2020-08-20 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-21 (33)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
		Study Treatment Admin/Dispense	P07.06: Nasopharyngeal swab sample not collected when required per protocol P05.09: Participant received less than 2 doses of IP during the study participation
US3772120	2020-12-27 (129)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3772128	2020-08-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-16 (117)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772128	2021-02-08 (171)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-20 (183)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-22 (185)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-24 (187)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-26 (189)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-18 (209)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3772140	2020-09-30 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3772146	2020-09-26 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772155	2020-09-20 (25)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-05 (132)	Inv Communication with Ethics	I04.01: Site did not communicate with Ethics as per Ethics Reporting requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772158	2020-08-26 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3772161	2020-09-21 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3772165	2020-11-22 (87)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3772172	2020-09-25 (29)	Study Treatment Admin/Dispense	P05.10: IP stored outside the required temperature range and administered to a subject
US3772188	2021-01-26 (149)	Inv Record Keeping Source Docs	I10.01: Persistent inadequate source documents after re-education
US3772202	2020-09-02 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772217	2020-09-03 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3772233	2020-11-09 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3772237	2020-09-10	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol Study Treatment Admin/DispenseP05.09: Participant received less than 2 doses of IP during the study participation
US3772247	2020-09-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-18 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3772259	2020-10-20 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3772261	2020-09-26 (16)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3782015	2020-09-09 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3782027	2021-01-21 (160)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3782119	2021-01-02 (125)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3782146	2020-10-29 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3782162	2020-09-08 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2021-01-20 (135)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3782176	2020-11-30 (56)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3782185	2021-01-02 (79)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3792012	2020-08-12 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3792016	2020-09-11 (31)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3792017	2020-08-13 (1)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3792018	2020-09-09 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3792039	2020-09-04 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-10-26 (53)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3792044	2020-09-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3792048	2020-09-14 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-11-08 (56)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3792071	2020-11-02 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3792075	2020-10-26 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3792082	2020-09-30 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
	2020-10-30 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3792085	2020-11-19 (49)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3792093	2020-10-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3802003	2020-08-25 (9)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-09-21 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802017	2020-09-18 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802018	2020-09-17 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-02-19 (183)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3802026	2020-09-21 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802026	2020-10-20 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802031	2020-08-24 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802056	2021-01-15 (142)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3802059	2020-08-26 (-1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3802074	2020-11-17 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3802097	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3802102	2020-10-27 (56)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802110	2020-11-20 (80)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802112	2020-09-30 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802121	2020-10-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802129	2021-01-15 (135)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3802147	2020-09-07 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3802171	2020-10-05 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802176	2020-09-08	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3802178	2020-10-06 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802197	2020-10-06 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802212	2020-09-09 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3802224	2021-01-05 (117)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3802226	2020-11-06 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802232	2020-10-13 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3802249	2020-11-09 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-11-16 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3802254	2020-09-14 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3802263	2020-10-19 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3812001	2020-08-13 (11)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3812004	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3812010	2020-08-10 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3812035	2020-11-10 (99)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
US3812037	2020-08-20 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3812038	2020-08-11 (8)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3812058	2020-08-20 (15)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-31 (148)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812062	2020-08-07 (2)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3812076	2020-10-09 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812080	2020-09-07 (32)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3812084	2021-03-04 (209)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3812085	2020-09-01 (25)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3812098	2020-11-04 (87)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3812121	2020-10-04 (55)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812128	2020-11-24 (106)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3812135	2020-08-12 (1)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3812148	2021-01-07 (149)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812158	2020-10-15 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812160	2020-08-20 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3812161	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3812179	2020-08-15 (1)	Inv Adequate Resources	I03.01: Untrained staff performing study procedures on subjects
US3812205	2020-08-23 (6)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3812225	2020-08-20 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3812237	2020-08-20 (-1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3812256	2020-09-28 (35)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3812263	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3812267	2021-02-05 (164)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3812301	2020-09-28 (32)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2020-11-02 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812303	2020-11-09 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3812328	2020-10-28 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3812335	2020-10-27 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (69)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3812344	2020-11-25 (62)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822002	2020-08-18 (15)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822004	2020-09-28 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822010	2020-08-27 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3822021	2020-08-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822043	2020-08-27 (21)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3822050	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822054	2020-08-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-15 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822054	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822061	2020-08-31 (22)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-09 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822072	2020-10-05 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822074	2020-08-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3822078	2020-08-11 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822082	2020-08-11 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822087	2020-09-08 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822087	2020-09-08 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-29 (80)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822088	2020-08-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-09 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3822089	2021-01-13 (155)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822094	2020-10-15 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822095	2020-09-17 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822109	2020-09-08 (27)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-19 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822113	2020-09-21 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822115	2020-09-15 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-08 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822117	2020-08-13 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822120	2020-09-18 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822121	2020-09-18 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822121	2020-09-18 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822123	2020-10-07 (56)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822126	2020-10-16 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822133	2020-10-15 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822149	2020-09-18 (33)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3822169	2020-09-09 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3822170	2020-09-21 (35)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3822177	2020-09-23 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822181	2020-09-24 (37)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822183	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3822184	2020-09-24 (37)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822185	2020-10-08 (29)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-30 (51)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822186	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822189	2020-09-24 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822189	2020-09-24 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822195	2020-11-06 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822204	2020-09-22 (34)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
	2020-10-21 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822208	2020-09-25 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822209	2020-10-22 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822212	2020-11-13 (86)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822215	2020-09-18 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-26 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822218	2020-09-24 (35)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822224	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-23 (34)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822237	2020-09-21 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-23 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
			P07.10: Subject Diary not completed 30 min post dosing
		Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822247	2020-09-29 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822248	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (39)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822251	2020-09-23 (30)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822261	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-21 (58)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3822265	2020-09-23 (30)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822266	2020-09-24 (31)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822268	2020-09-29 (35)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822269	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-09-23 (29)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822271	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3822275	2020-09-23 (29)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3822291	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822293	2020-09-18 (23)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822293	2021-02-24 (182)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3822324	2020-08-31 (1)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
US3822360	2020-09-03 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3822395	2020-10-15 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3822399	2020-10-23 (38)	Missing Endpoint Assessments Study Treatment Admin/Dispense Visit Scheduling	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3822404	2020-09-08 (-9)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3822405	2020-10-23 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822405	2020-10-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822416	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822419	2020-10-20 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3822434	2020-11-06 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3822437	2020-11-03 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3822449	2021-02-17 (140)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-19 (142)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3822450	2020-10-30 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3822457	2020-10-19 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3822464	2020-11-18 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832003	2020-07-30 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832005	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832006	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832006	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832009	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832010	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832013	2020-07-31 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
		Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832015	2020-07-31 (1)	Exclusion Criteria Missing Endpoint Assessments	P03.01: Exclusion criteria met, but subject randomized P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832018	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832020	2020-07-31 (1)	Exclusion Criteria Missing Endpoint Assessments	P03.01: Exclusion criteria met, but subject randomized P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832021	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832021	2020-07-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832024	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832025	2020-07-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3832030	2020-08-01 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832038	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832045	2020-08-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832051	2020-08-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832055	2020-09-07 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-09-09 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3832066	2020-09-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832067	2020-08-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2021-01-13 (163)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3832117	2020-08-06 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832119	2020-12-07 (124)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3832140	2020-08-10 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3832167	2020-08-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3832173	2020-08-12 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3832185	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3832197	2020-09-15 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832201	2021-02-17 (185)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3832206	2020-08-17 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3832242	2020-08-21 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-09-18 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832264	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3832274	2020-09-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-12-02 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-02 (96)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3842003	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-09 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3842010	2020-11-19 (80)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3842013	2020-11-19 (79)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3842023	2021-01-20 (135)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3842025	2020-11-19 (65)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3842027	2020-11-19 (71)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3842051	2021-03-03 (149)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3852002	2020-09-04 (16)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852002	2020-10-21 (63)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
US3852003	2020-09-04 (16)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852006	2020-09-04 (15)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3852007	2020-09-04 (15)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3852008	2020-09-04 (12)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3852027	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852040	2020-08-26 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852047	2020-09-29 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852052	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-26 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852056	2020-08-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3852069	2020-10-06 (37)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3852076	2020-12-01 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852082	2021-03-24 (205)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852091	2020-09-02 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3852108	2020-11-10 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-24 (112)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3852110	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852115	2020-09-04 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
US3852120	2020-09-04 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3852132	2020-09-08 (-1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852141	2020-09-09 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3852145	2020-10-08 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852150	2020-09-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3852151	2020-11-11 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852156	2020-09-10 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
US3852160	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-10 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852171	2020-09-11 (1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852177	2020-10-11 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3852183	2020-10-23 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-20 (67)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-12-04 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3852192	2020-09-22 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-20 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3852193	2020-09-23 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-20 (152)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3852193	2021-02-27 (159)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-03-04 (164)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3862001	2021-01-06 (153)	ICF Process/Timing	I02.02: Wrong informed consent version signed
	2021-03-10 (216)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862003	2020-09-14 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-01-06 (149)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862023	2020-09-14 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-12-15 (121)	Study Procedures/Assessments	P07.10: Subject Diary not completed 30 min post dosing P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862028	2020-09-14 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862028	2020-12-15 (120)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862034	2020-08-26 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-02-11 (177)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862037	2021-02-05 (171)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862039	2020-09-16 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862041	2020-08-20 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3862084	2021-03-01 (186)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862092	2020-09-14 (15)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-12 (43)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-02-05 (159)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862100	2020-09-28 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862100	2021-01-15 (137)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862110	2021-02-22 (174)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862119	2021-01-25 (145)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862121	2020-12-15 (104)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862125	2021-03-01 (180)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862128	2021-02-22 (172)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862143	2020-10-05 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862154	2020-10-20 (42)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2021-02-11 (156)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862159	2020-09-09 (1)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
	2020-12-04 (87)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862167	2020-12-03 (85)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3862181	2021-01-20 (129)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862184	2020-10-12 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-03 (143)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3862186	2021-01-25 (134)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862192	2021-01-22 (130)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862201	2021-02-23 (161)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862203	2020-12-15 (91)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3862205	2020-09-16 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3862218	2020-12-15 (89)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862225	2020-10-22 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862237	2020-10-28 (35)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-12-15 (83)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862242	2020-12-15 (83)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862251	2020-11-30 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3862259	2021-03-16 (169)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3862261	2020-10-27 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862262	2020-12-16 (79)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862274	2020-10-28 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862277	2020-12-03 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3862278	2020-12-03 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3862280	2020-11-04 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3862285	2021-01-26 (104)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862292	2021-01-22 (94)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862294	2020-11-20 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2021-03-09 (139)	ICF Process/Timing	I02.02: Wrong informed consent version signed
US3862295	2020-11-25 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3862296	2020-10-22 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-23 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872001	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872009	2020-08-27 (28)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872011	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872013	2020-08-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872016	2020-08-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-29 (58)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872020	2020-12-04 (124)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872020	2020-12-06 (126)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2020-12-07 (127)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-08 (128)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3872025	2020-09-15 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872026	2020-08-13 (11)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872030	2020-09-09 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872044	2020-08-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-08-13 (10)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-04 (123)	Missing Endpoint Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872046	2020-09-15 (43)	ICF Process/Timing	I02.05: Informed consent not signed prior to any study procedure
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-27 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872051	2020-09-02 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872052	2020-08-08 (4)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3872056	2020-09-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-13 (70)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3872059	2020-09-09 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872066	2020-09-15 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872066	2020-11-24 (111)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872071	2020-09-03 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3872090	2020-09-18 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872096	2020-09-04 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872110	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872118	2020-10-30 (82)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872122	2020-09-15 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872139	2020-09-22 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872139	2020-09-22 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872150	2020-10-23 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872152	2020-10-27 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872153	2020-09-09 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872156	2020-09-18 (38)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3872159	2020-10-26 (76)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872161	2020-08-12 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872167	2020-10-23 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872168	2020-08-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3872186	2020-09-23 (41)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3872189	2020-10-30 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872197	2020-08-14 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3872198	2020-12-04 (113)	Missing Endpoint Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3872202	2020-09-11 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872202	2020-11-09 (88)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872210	2020-10-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872212	2020-10-23 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872221	2020-10-26 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872225	2020-10-26 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872226	2021-02-19 (185)	Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, administration error
US3872239	2020-11-05 (79)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872250	2020-10-23 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872254	2020-09-28 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872254	2020-09-28 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872255	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3872261	2020-10-06 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-10 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872262	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872267	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872268	2020-10-19 (57)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872269	2020-10-19 (57)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872269	2020-10-19 (57)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872274	2020-09-29 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872276	2020-10-28 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-09 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872281	2020-09-30 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872283	2020-09-30 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872285	2020-10-02 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-09 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872290	2021-01-27 (156)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872291	2020-10-05 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872291	2020-11-05 (73)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3872293	2020-10-06 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872294	2020-10-01 (38)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872296	2020-09-22 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872297	2020-10-05 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872298	2020-10-01 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872306	2020-10-13 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872306	2020-11-23 (90)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872309	2020-10-14 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872310	2020-10-14 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (92)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872313	2020-09-23 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872318	2020-09-24 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872319	2020-09-24 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-30 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872321	2020-09-24 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872325	2020-09-24 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-04 (39)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3872332	2020-10-09 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872341	2020-08-27 (-1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872348	2020-09-25 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872351	2020-09-25 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-12 (77)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872366	2020-10-15 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872368	2020-10-16 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872370	2020-10-06 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872371	2020-09-26 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872372	2020-10-09 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872374	2020-10-08 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872375	2020-10-15 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872375	2020-11-19 (83)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872378	2020-10-08 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872379	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872382	2020-10-06 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872383	2020-10-13 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-23 (85)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872388	2020-09-28 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872391	2020-10-06 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-18 (80)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872392	2020-10-06 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872394	2020-10-09 (40)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3872396	2020-09-28 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872397	2020-09-28 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872409	2020-12-10 (101)	Inv Safety Rptg (Reg/Sponsor) Missing Endpoint Assessments	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness P07.07: Saliva sample not collected when required per protocol
US3872410	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3872411	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3872413	2020-10-16 (46)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3872416	2020-10-13 (42)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872416	2020-11-24 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872417	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-14 (135)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3872421	2020-10-14 (43)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-18 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872423	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-01 (91)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872425	2020-09-30 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872426	2020-10-19 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872427	2020-10-20 (49)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872429	2020-09-09 (8)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872431	2020-10-20 (49)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872432	2020-10-19 (48)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872437	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872439	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872441	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872443	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872443	2020-11-19 (78)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872444	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872445	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872452	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872453	2020-10-01 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872460	2020-11-19 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872463	2020-10-13 (40)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872469	2020-10-16 (39)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872469	2020-10-16 (39)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872474	2020-11-18 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872479	2020-09-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-06 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872481	2020-11-18 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872485	2020-10-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872489	2020-10-07 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3872490	2020-10-19 (41)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

Day is defined as study day from first injection date.

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3872493	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3872506	2020-10-08 (29)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3882002	2020-08-27 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3882005	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882008	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3882010	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-02-02 (153)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3882014	2020-09-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3882015	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882016	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882020	2020-09-04 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882021	2020-09-04 (1)	Missing Endpoint Assessments Study Treatment Randomization	P07.10: Subject Diary not completed 30 min post dosing P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3882037	2020-10-09 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.10: Subject Diary not completed 30 min post dosing
US3882038	2020-10-12 (-1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3882038	2020-10-13 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882043	2020-10-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-12 (30)	Study Treatment Admin/Dispense	P05.05: Use of study treatment at V2 impacted by a temperature excursion which was not reported or approved or which was disapproved for further use
US3882045	2020-10-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882048	2020-10-22 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3882070	2020-11-24 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3882071	2020-12-15 (54)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3892001	2020-08-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3892001	2020-09-21 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3892017	2020-11-16 (78)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3892025	2020-08-28 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3892033	2021-01-06 (129)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3892039	2020-09-21 (21)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3892054	2020-10-05 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3892070	2020-09-16 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3892073	2020-10-09 (30)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902002	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902003	2020-08-31 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902007	2020-09-29 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902020	2020-10-07 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3902024	2020-10-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
US3902026	2020-09-10 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902030	2020-09-08 (6)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-01 (29)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3902031	2020-09-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-01 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3902037	2021-02-17 (167)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3902041	2020-10-12 (35)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3902044	2020-11-03 (57)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3902067	2020-10-08 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3902075	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902076	2020-09-11	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3902081	2020-10-13 (30)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.02: Subject not given correct treatment provided by IRT, dispensation error
US3902099	2020-11-19 (64)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-19 (125)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days
US3902110	2020-10-19 (27)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-10-26 (34)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3902113	2020-09-25	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3902114	2020-09-25	ICF Process/Timing Inclusion Criteria	I02.03: Informed consent not signed and/or dated by subject P02.01: Inclusion criteria not met, but subject randomized
US3902131	2020-10-16	Inclusion Criteria Missing Endpoint Assessments	P02.01: Inclusion criteria not met, but subject randomized P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3902139	2021-01-14 (84)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912024	2020-10-22 (56) 2020-10-27 (61)	Study Procedures/Assessments Missing Endpoint Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912029	2020-08-31 (4)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3912033	2020-08-29 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912033	2020-09-21 (24)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3912047	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3912061	2020-10-07 (37)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3912068	2020-09-01 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3912083	2021-01-07 (128)	Study Procedures/Assessments	P08.15: Unblinded study procedure not completed per protocol and/or pharmacy manual requirements
US3912114	2020-09-04 (1)	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
	2020-09-30 (27)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-30 (57)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912128	2020-09-14 (7)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912132	2020-11-11 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912133	2020-10-28 (51)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912134	2020-11-18 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912152	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912166	2020-10-13 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3912169	2020-10-27 (42)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3912176	2020-11-30 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3912182	2020-10-15 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912184	2020-10-23 (36)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912198	2020-10-22 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3912200	2020-10-23 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3912204	2020-10-21 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3912205	2020-10-30 (38)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
US3912224	2020-10-28 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3912235	2020-10-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-12-17 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3912235	2021-02-08 (124)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3922004	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3922023	2020-08-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3922036	2020-09-09 (15)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-10-07 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-12 (48)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3922038	2020-10-22 (58)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
US3922043	2020-09-28 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3922050	2020-10-05 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922050	2020-10-05 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3922061	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-05 (36)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3922070	2020-10-09 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3922076	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3922079	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3922080	2020-09-03 (1)	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2020-10-02 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922084	2021-02-06 (152)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3922094	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3922095	2020-11-13 (66)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3922098	2020-09-16 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3922112	2021-02-12 (151)	Missing Endpoint Assessments	P07.05: Lab samples not collected per protocol for subjects suspected of COVID-19 during the 28 day follow up
	2021-02-23 (162)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
US3922114	2020-10-15 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922115	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3922136	2020-11-30 (50)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window
US3922137	2020-10-12 (1) 2020-12-02 (52)	Study Treatment Randomization Study Treatment Admin/Dispense Visit Scheduling	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum) P05.09: Participant received less than 2 doses of IP during the study participation P10.01: Onsite Visits not performed or out of window
US3922139	2020-10-30 (19)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3922144	2020-11-12 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3922153	2021-01-16 (87)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 4 days

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3922161	2020-11-24 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932007	2020-09-22 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3932008	2020-09-28 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2021-02-06 (165)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3932012	2020-09-24 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932033	2020-10-05 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932037	2020-10-03 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932039	2020-10-07 (38)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3932044	2020-09-30 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932047	2020-10-06 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932055	2020-09-02 (1)	Study Procedures/Assessments	P08.01: Subject was not observed for at least 30 minutes after vaccination
	2020-10-01 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-22 (82)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932063	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-06 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932064	2020-09-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932064	2020-10-03 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932070	2020-10-08 (36)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-10-12 (40)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-16 (75)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932071	2020-09-04 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932073	2020-09-28 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932077	2021-02-26 (176)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3932092	2020-10-07 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932095	2020-12-01 (84)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3932097	2020-09-10 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-08 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932098	2020-10-13 (34)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932102	2020-09-10 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3932108	2020-10-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P07.10: Subject Diary not completed 30 min post dosing
	2020-11-13 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932121	2020-11-13 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932122	2020-11-17 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932131	2020-09-23 (10)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-09 (26)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3932134	2020-10-28 (44)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-25 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932141	2020-10-28 (43)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932142	2021-02-22 (160)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
	2021-02-23 (161)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932145	2020-09-15 (-1)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-11-18 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932146	2020-10-27 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932150	2020-10-22 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-07 (53)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3932151	2020-10-23 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932160	2020-10-29 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932169	2020-10-27 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-01-07 (108)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932172	2020-10-28 (36)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-12-02 (71)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932180	2020-09-24 (1)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3932185	2020-11-12 (50)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932189	2020-10-29 (35)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-31 (98)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3932190	2020-10-23 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932194	2020-10-14 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932202	2020-09-26 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932202	2020-12-03 (69)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
	2020-12-07 (73)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3932206	2020-11-03 (37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-11-05 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-01-22 (117)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
US3932207	2020-09-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932215	2020-10-29 (30)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3932217	2020-10-02 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3932220	2020-10-28 (26)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932222	2020-10-30 (28)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-30 (59)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3932223	2020-10-03 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-10-22 (20)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-31 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
	2020-11-03 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
		Study Treatment Admin/Dispense	P05.07: Subsequent vaccine administered while contraindicated for a visit (e.g.: Pre-Vaccination Body Temperature =38.0°C/100.4°F)
	2020-12-09 (68)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-31 (90)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932223	2021-01-02 (92)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
	2021-01-22 (112)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2021-01-24 (114)	Study Procedures/Assessments	P08.13: Subjects suspected of COVID-19 did not have Lab samples collected during the 28 day follow up (Nasopharyngeal swab within 72hrs for RT-PCR testing, or saliva sample or nasal swab)
US3932224	2020-11-02 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932246	2020-10-12 (-1)	ICF Process/Timing	I02.04: Informed consent not signed and/or dated by appropriate site staff
	2020-11-27 (46)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3932248	2020-10-14 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-18 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3932267	2020-11-09 (26)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3932288	2020-10-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3932291	2020-10-19 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-17 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942002	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-01 (12)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3942004	2020-08-21 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-08-27 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942007	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3942009	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-25 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942016	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3942048	2020-09-05 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-03 (32)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942049	2020-11-12 (72)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3942051	2020-09-05 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942061	2020-10-09 (37)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-10-14 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942064	2020-10-05 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942068	2020-11-23 (81)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3942105	2020-10-26 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3942107	2020-09-22	Exclusion Criteria	P03.01: Exclusion criteria met, but subject randomized
	2020-09-23	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942125	2020-10-19 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-10-25 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942131	2020-10-25 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942133	2020-09-26 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-29 (35)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942138	2020-10-02 (3)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-02 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942139	2020-10-06 (2)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942139	2020-11-16 (43)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2021-03-17 (164)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3942145	2020-10-14 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-12 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-11-18 (42)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942153	2020-11-08 (28)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2020-11-13 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942154	2020-10-19 (8)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3942155	2020-11-18 (38)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3942155	2020-11-18 (38)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
	2020-12-29 (79)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3942158	2020-11-15 (33)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3942159	2020-12-21 (69)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952004	2020-12-22 (110)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3952012	2020-09-28 (29)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3952019	2020-12-30 (121)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3952020	2020-09-04 (4)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952024	2020-09-10 (10)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
	2020-10-08 (38)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3952026	2020-10-02 (32)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3952036	2020-10-05 (33)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3952052	2021-02-11 (157)	Study Procedures/Assessments	P08.10: Subjects suspected of COVID-19 not assessed within 72 hrs
US3952082	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3952083	2020-12-09 (87)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3952092	2020-10-15 (31)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2021-03-01 (168)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952096	2020-09-15 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3952100	2021-01-09 (115)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3952145	2020-10-22 (29)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3952147	2020-10-22 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3952149	2020-09-24 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-03-12 (170)	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3952166	2020-12-09 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952172	2020-10-03 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3952172	2020-10-27 (29)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
US3952180	2020-12-11 (73)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952190	2020-10-05 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3952197	2020-10-10 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-10 (36)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3952224	2020-11-11 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3962021	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3962055	2020-09-02 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3962058	2020-10-01 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3962063	2021-03-02 (181)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
US3962072	2020-11-09 (67)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3962083	2020-09-12 (5)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3962094	2020-11-09 (62)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3962105	2020-12-02 (65)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3972006	2020-08-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972010	2020-08-24 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972016	2020-08-24 (1)	Missing Endpoint Assessments	P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination) P07.10: Subject Diary not completed 30 min post dosing
US3972017	2020-08-24 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972020	2020-09-28 (35)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3972043	2020-08-27 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972045	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-24 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972048	2020-08-27 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972051	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972055	2020-08-28 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972059	2020-09-25 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972064	2020-08-31 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972065	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972076	2020-09-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972084	2020-09-29 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972093	2020-09-02 (1)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3972097	2020-09-03 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1) P07.04: Subject Diary not completed (in entirety) for safety data collection (post vaccination)
	2021-01-27 (147)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3972100	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-11-05 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3972103	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972104	2020-09-03 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-01 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972117	2020-09-04 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-07 (34)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972118	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972123	2020-10-06 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972131	2020-09-08 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972135	2020-09-09 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3972137	2020-11-11 (63)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3972156	2020-10-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972167	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-15 (31)	Study Procedures/Assessments	P08.05: Pregnancy tests not performed as specified by the protocol (female subjects)
US3972170	2020-09-15 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972207	2020-10-19 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3972210	2020-09-22 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3972213	2020-09-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972221	2020-10-13 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-11-30 (49)	Study Treatment Admin/Dispense	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2) P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3972223	2020-10-01 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3972225	2020-10-19 (8)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol
	2020-10-20 (9)	Study Procedures/Assessments	P08.14: Subjects that had the Illness Visit and tested positive for COVID-19 were not monitored for a 14-day period after diagnosis or until symptoms were resolved, whichever was later
	2020-10-26 (15)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982007	2020-08-25 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982023	2021-01-08 (135)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
US3982040	2020-08-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982049	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982055	2020-08-31 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982066	2020-09-28 (28)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3982070	2020-09-01	Inclusion Criteria	P02.01: Inclusion criteria not met, but subject randomized
		Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982070	2020-09-01	Missing Endpoint Assessments	P07.06: Nasopharyngeal swab sample not collected when required per protocol
		Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2020-10-16	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982093	2020-10-16 (44)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3982098	2020-11-11 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982110	2021-02-27 (177)	Inv Safety Rptg (Reg/Sponsor)	I12.01: Serious Adverse Event/AESI not reported within 24 hours of site awareness
	2021-03-11 (189)	Study Procedures/Assessments	P08.12: Subjects confirmed of COVID-19 have missed visits during the 28 day follow up
US3982119	2020-10-15 (39)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
	2020-11-19 (74)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982121	2020-09-07 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982123	2020-09-13 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-06 (30)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982137	2020-10-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982157	2020-10-09 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982158	2020-09-11 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-09-29 (19)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
US3982172	2020-09-20 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3982182	2020-10-27 (42)	Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
		Visit Scheduling	P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982192	2020-10-26 (40)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
		Study Treatment Admin/Dispense	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7)
US3982203	2020-10-19 (31)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982211	2020-09-19 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-21 (33)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3982213	2020-09-21 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
	2020-10-09 (19)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation
	2021-02-20 (153)	Study Procedures/Assessments	P08.24: Subjects not confirmed of COVID-19 have missed visits during the 28 day follow up prior to receipt of negative COVID-19 results

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982213	2021-02-21 (154)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
	2021-02-23 (156)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3982224	2020-10-21 (29)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3982225	2020-09-23 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-22 (30)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3982241	2020-09-28 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3982244	2020-09-28 (1)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2020-10-23 (26)	Study Treatment Admin/Dispense	P05.09: Participant received less than 2 doses of IP during the study participation

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3982247	2020-10-05 (7)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
US3982251	2020-12-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982252	2020-12-02 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3982264	2020-11-12 (29)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992003	2020-09-17 (1)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3992021	2020-11-02 (41)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992024	2020-08-17 (-37)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3992029	2020-11-07 (44)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992031	2020-09-26 (2)	Study Treatment Randomization	P04.01: Randomized under incorrect stratification (e.g.subject assigned to wrong stratum)
US3992033	2020-08-17 (-39)	Missing Endpoint Assessments	P07.10: Subject Diary not completed 30 min post dosing
US3992049	2020-11-30 (62)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992050	2020-12-09 (70)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992052	2020-12-03 (64)	Visit Scheduling	P10.01: Onsite Visits not performed or out of window
US3992056	2020-10-23 (22)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992058	2020-10-23 (22)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992067	2020-11-16 (42)	Study Treatment Admin/Dispense Visit Scheduling	P05.03: 2nd dose occurred out of window (28 days -3 /+ 7) P10.01: Onsite Visits not performed or out of window

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992073	2020-10-23 (16)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 2)
US3992086	2020-10-10 (1)	ICF Process/Timing	I02.03: Informed consent not signed and/or dated by subject
US3992100	2020-10-14 (1)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
	2020-11-18 (36)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3992102	2020-11-07 (25)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject
US3992109	2020-12-30 (76)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol
US3992113	2020-10-26 (8)	Missing Endpoint Assessments	P07.03: Subject Diary has 2 or more consecutive days of solicited entries missing within one segment (post Dose 1)
	2021-01-05 (79)	Missing Endpoint Assessments	P07.07: Saliva sample not collected when required per protocol
US3992126	2020-12-21 (61)	Concomitant Medication	P09.01: Prohibited concomitant medication or vaccine received by subject

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Listing 16.2.2.2
Major Protocol Deviations
Randomization Set

Treatment Group: mRNA-1273

Subject ID	Date of Deviation (Day)	Deviation	Description
US3992126	2020-12-21 (61)	Study Treatment Admin/Dispense	P05.15: Subject received EUA vaccine outside of study before the subject discontinued from the study
	2020-12-31 (71)	Missing Endpoint Assessments	P07.01: Blood sample not taken when required per protocol P07.06: Nasopharyngeal swab sample not collected when required per protocol

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