16.1.2 Sample Case Report Form (Unique Pages Only)

This section contains the following document:

Case Report Form v2.039 EAB, dated 23 July 2020

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Participant Creation
Generated On: 27 Jul 2020 15:10:41

Participant ID _____

mRNA-1273-P201 Completion Guidelines _____

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Visit Date
Generated On: 27 Jul 2020 15:10:41

Was this visit performed?	Yes ☐ No ☐
Visit date (dd MMM yyyy)	
Has participant been exposed or potentially exposed to COVID-19?	Yes ☐ No ☐
Is participant COVID-19 symptomatic? *Only record new symptoms since the last visit*	Yes ☐ No ☐
Folder OID	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Unscheduled Visit Assessment
Generated On: 27 Jul 2020 15:10:41

Check all that apply	
Physical Exam	
Vital Signs	
Central Laboratory	
Central Laboratory - Antibody-Mediated Immunogenicity	
Central Laboratory - Nasopharyngeal Swab and Blood Collection for SARS-CoV-2	
Pregnancy Test	
Local Diagnostic Test	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Demographics
Generated On: 27 Jul 2020 15:10:41

Date of Birth (MMM yyyy)	
Age	
Age Units	
Age (Derived)	
Sex	Female ☐
	Male ☐
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ☐
	Not Reported ☐
	Unknown ☐
Race (Check All That Apply)	
White	
Black	
Asian	
American Indian or Alaska Native	
Native Hawaiian or other Pacific Islander	
Other	
If race is Other, specify	
Unknown	
Not reported	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Enrollment
Generated On: 27 Jul 2020 15:10:41

Date of Informed Consent *(dd MMM yyyy)*	
Month and Year of Informed Consent (derived)	
Year of Informed Consent (derived)	
Protocol Version	Original ☐
	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☐
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☐
If Yes, previous participant number	
Enrollment Trigger	

Did the participant meet all eligibility criteria?	Yes ☐ No ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Inclusion/Exclusion Criteria
Generated On: 27 Jul 2020 15:10:41

Select inclusion criteria not met and/or exclusion criteria met

Criterion Type	Inclusion ☐
	Exclusion ☐
Criterion Identifier	1 ☐
	2 ☐
	3 ☐
	4 ☐
	5 ☐
	6 ☐
	7 ☐
	8 ☐
	9 ☐
	10 ☐
	11 ☐
	12 ☐
	13 ☐
	14 ☐
	15 ☐
	16 ☐
	17 ☐
	18 ☐
	19 ☐
	20 ☐
	21 ☐
	22 ☐
	23 ☐
	24 ☐
	25 ☐
	26 ☐
	27 ☐
	28 ☐
	29 ☐
	30 ☐

Were any significant conditions reported??	Yes ☐ No ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Medical History
Generated On: 27 Jul 2020 15:10:41

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes ☐ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Vital Signs
Generated On: 27 Jul 2020 15:10:41

Were vital signs assessed?	Yes ☐ No ☐
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	Fixed Unit: (24 HR)
Vital Signs Date and Time (derived)	
Height *(xxx.x)*	**cm** ☐ in ☐
Weight *(xxx.x)*	**kg** ☐ lb ☐
BMI *(xxx.x)*	Fixed Unit: kg/m^2
BMI units	
Temperature *(xxx.x)*	**C** ☐ F ☐
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	Fixed Unit: beats/min
Pulse units	
Respiratory Rate *(xxx)*	Fixed Unit: breaths/min
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Diastolic Blood Pressure units	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Vital Signs - Dosing
Generated On: 27 Jul 2020 15:10:41

Height	**cm** ☐ in ☐
Weight	**kg** ☐ lb ☐
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ☐ No ☐
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	Fixed Unit: (24 HR)
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	**C** ☐ F ☐
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	Fixed Unit: beats/min
Pulse units	
Respiratory Rate *(xxx)*	Fixed Unit: breaths/min
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Diastolic Blood Pressure units	
Timepoint	Pre-Dose ☐ Post-Dose ■

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Vital Signs - Dosing
Generated On: 27 Jul 2020 15:10:41

Were vital signs assessed?	Yes ☐ No ☐
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	Fixed Unit: (24 HR)
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	**C** ☐ F ☐
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	Fixed Unit: beats/min
Pulse units	
Respiratory Rate *(xxx)*	Fixed Unit: breaths/min
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Diastolic Blood Pressure units	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Physical Examination
Generated On: 27 Jul 2020 15:10:41

Was the physical examination performed?	Yes ☐ No ☐
Date of examination *(dd MMM yyyy)*	

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

Collection date *(dd MMM yyyy)*	
Lab panel	Hematology ☑ Chemistry ☐ Serology ☐ Coagulation ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ☑ Serology ☐ Coagulation ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ☐ Serology ☐ Coagulation ☑
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

Collection date *(dd MMM yyyy)*	
Lab panel	Hematology ■ Chemistry ☐ Serology ☐ Coagulation ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ■ Serology ☐ Coagulation ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ☐ Serology ■ Coagulation ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ☐ Serology ☐

	Coagulation ■
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

Collection date *(dd MMM yyyy)*	
Lab panel	Hematology ■ Chemistry ☐ Serology ☐ Coagulation ☐ FSH ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ■ Serology ☐ Coagulation ☐ FSH ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	
Lab panel	Hematology ☐ Chemistry ☐ Serology ■ Coagulation ☐ FSH ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Central Laboratory with FSH/Serology
Generated On: 27 Jul 2020 15:10:41

Lab panel	Hematology ☐ Chemistry ☐ Serology ☐ Coagulation ■ FSH ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

Lab panel	Hematology ☐ Chemistry ☐ Serology ☐ Coagulation ☐ FSH ■
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 27 Jul 2020 15:10:41

Collection date *(dd MMM yyyy)*	
Lab Test	Nasopharyngeal Swab 1 ■ Nasopharyngeal Swab 2 ☐ Blood Collection for exposure to SARS-CoV-2 ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00 - 23:59)*	
Collection date and time (derived)	
Lab Test	Nasopharyngeal Swab 1 ☐ Nasopharyngeal Swab 2 ■ Blood Collection for exposure to SARS-CoV-2 ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00 - 23:59)*	
Collection date and time (derived)	

Collection date *(dd MMM yyyy)*	
Lab Test	Nasopharyngeal Swab 1 ■ Nasopharyngeal Swab 2 ☐ Blood Collection for exposure to SARS-CoV-2 ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00 - 23:59)*	
Collection date and time (derived)	
Lab Test	Nasopharyngeal Swab 1 ☐ Nasopharyngeal Swab 2 ■ Blood Collection for exposure to SARS-CoV-2 ☐
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00 - 23:59)*	
Collection date and time (derived)	
Lab Test	Nasopharyngeal Swab 1 ☐ Nasopharyngeal Swab 2 ☐ Blood Collection for exposure to SARS-CoV-2 ■
Was the sample collected?	Yes ☐ No ☐
Collection time *(00:00 - 23:59)*	
Collection date and time (derived)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Unscheduled
Generated On: 27 Jul 2020 15:10:41

Collection date *(dd MMM yyyy)*	
Lab panel	Hematology ☐ Chemistry ☐ Coagulation ☐ Other ☐
If Other, specify	
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Childbearing Potential
Generated On: 27 Jul 2020 15:10:41

Date of assessment *(dd MMM yyyy)*	
Is the participant of childbearing potential?	Yes ☐
	No ☐
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☐
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Pregnancy Test
Generated On: 27 Jul 2020 15:10:41

Was the pregnancy test performed?	Yes ☐ No ☐
Date of test *(dd MMM yyyy)*	_____
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Randomization
Generated On: 27 Jul 2020 15:10:41

What was the date of randomization? *(dd MMM yyyy)*	_____
What was the participant's randomization number?	_____
In what Cohort was the participant enrolled?	Cohort 1: Age >= 18 to < 55 mRNA-1273 or Placebo ☐ Cohort 2: Age >= 55 mRNA-1273 or Placebo ☐
Was this a Sentinel participant?	Yes ☐ No ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Exposure
Generated On: 27 Jul 2020 15:10:41

Was study treatment given?	Yes ☐ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	Fixed Unit: (24 HR)
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ☐ Right Arm ☐
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Antibody-Mediated Immunogenicity
Generated On: 27 Jul 2020 15:10:41

Lab panel	Antibody-mediated Immunogenicity
Was the sample collected?	Yes No
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)
Collection date and time (derived)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Safety Call
Generated On: 27 Jul 2020 15:10:41

Was Contact Attempted?	Yes ☐ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	_____
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	_____
Has participant been exposed or potentially exposed to COVID-19?	Yes ☐ No ☐
Is participant COVID-19 symptomatic? *Only record new symptoms since the last visit*	Yes ☐ No ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: SARS-CoV-2 or COVID-19 Exposure Assessment
Generated On: 27 Jul 2020 15:10:41

Has the participant had close contact with a person known to have SARS-CoV-2 infection or COVID-19?	Yes ☐ No ☐

If yes, how was the participant exposed? (check all that apply)

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: SARS-CoV-2 or COVID-19 Symptoms Assessment
Generated On: 27 Jul 2020 15:10:41

Does the participant have symptoms of potential COVID-19?	Yes ☐ No ☐
Estimated date of first symptoms	

(If Yes, check all symptoms that apply)

Only record new symptoms since the last visit	
Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	
Please enter any other symptoms, one per line, in the log section below	
If Other, Specify	

Vaccination Dose	Dose 1 ☐ Dose 2 ☐
Days Relative to Vaccination	Day of vaccination ☐ 1 day from vaccination ☐ 2 days from vaccination ☐ 3 days from vaccination ☐ 4 days from vaccination ☐ 5 days from vaccination ☐ 6 days from vaccination ☐
Was rash evaluated by a healthcare provider?	Yes ☐ No ☐
If Yes, Investigator Site or Other Institution	
Investigator Site	_____
Other Institution	_____
Date of rash assessment by site investigator *(dd MMM yyyy)*	_____
Rash Location	_____
What is the site investigator's assessment of the rash?	Grade 0 = No rash ☐ Grade 1 = Localized rash, without associated symptoms ☐ Grade 2 = maculopapular rash covering <50% body surface area ☐ Grade 3 = urticarial rash covering > 50% body surface area ☐ Grade 4 = Generalized exfoliative, ulcerative or bullous dermatitis, e.g. Stevens-Johnson syndrome or erythema multiforme ☐
Additional relevant information	_____

Vaccination Dose	Dose 1 ☐
	Dose 2 ☐
Days Relative to Vaccination	Day of vaccination ☐
	1 day from vaccination ☐
	2 days from vaccination ☐
	3 days from vaccination ☐
	4 days from vaccination ☐
	5 days from vaccination ☐
	6 days from vaccination ☐
Was lymphadenopathy evaluated by a healthcare provider?	Yes ☐
	No ☐

If Yes, Investigator Site or Other Institution

Investigator Site	_____
Other Institution	_____
Date of lymphadenopathy assessment by site investigator *(dd MMM yyyy)*	_____
Lymphadenopathy confirmed on physical exam?	Yes ☐
	No ☐
Additional relevant information	_____

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Local Diagnostic Test
Generated On: 27 Jul 2020 15:10:41

Date of Test	
Institution Name	
Diagnostic Test Performed	Nasopharyngeal Swab ☐ Blood Test ☐ Other ☐
Other, Specify	
Type of Diagnostic Test (if known):	
COVID-19 Result	Positive ☐ Negative ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 27 Jul 2020 15:10:41

Were any prior/concomitant medications and/or vaccinations taken?	Yes ☐ No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

Name of Medication	
Indication	
Dose per administration	
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐

	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	_____
Start date *(dd MMM yyyy)*	_____
Start date completely unknown	_____
Ongoing?	Yes ☐
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	_____
Was this medication taken for solicited event?	Yes ☐
	No ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Concomitant Procedures Summary
Generated On: 27 Jul 2020 15:10:41

Were any concomitant procedures performed?	Yes ☐
	No ☐

If yes, please complete Concomitant Procedures form.

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Concomitant Procedures
Generated On: 27 Jul 2020 15:10:41

Procedure/Surgery date *(dd MMM yyyy)*	
Procedure/Surgery	
Indication	Adverse Event ☐ Medical History ☐ Diagnostic ☐ Other ☐
If indication is Other, specify	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Adverse Events Summary
Generated On: 27 Jul 2020 15:10:41

Did the participant experience any adverse events?	Yes ☐ No ☐

If Yes, enter details on the Adverse Events form.

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Adverse Events
Generated On: 27 Jul 2020 15:10:41

Adverse event	
Was this a medically-attended AE?	Yes ☐ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☐
Start date *(dd MMM yyyy)*	
Start time *(00:00-23:59)*	Fixed Unit: (24 HR)
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	Fixed Unit: (24 HR)
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☐
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	

Other medically important event	
Relationship to investigational product	Not Related ☐ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	
Concomitant Medication	
Concomitant Procedure	
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Enter Narrative ONLY for Serious Adverse Events	
SAE Narrative	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Dosing Discontinuation
Generated On: 27 Jul 2020 15:10:41

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	Adverse Event (Other) ☐ Adverse Event (COVID-19 infection) ☐ Death ☐ Lost To Follow-up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated By Sponsor ☐ Withdrawal of Consent (Other) ☐ Withdrawal of Consent (COVID-19 non-infection related) ☐ Other ☐
If reason is Adverse Event (Other), Physician Decision, Withdrawal of Consent (Other), Withdrawal of Consent (COVID-19 non-infection related), Protocol Deviation or Other, specify	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: End of Study / Study Discontinuation
Generated On: 27 Jul 2020 15:10:41

Date of study discontinuation/completion *(dd MMM yyyy)*	
Reason for discontinuation	Adverse Event (Other) ☐ Adverse Event (COVID-19 infection) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated By Sponsor ☐ Withdrawal of Consent (Other) ☐ Withdrawal of Consent (COVID-19 non-infection related) ☐ Other ☐
If reason for discontinuation is Adverse Event (Other), Physician Decision, Withdrawal of Consent (Other), Withdrawal of Consent (COVID-19 non-infection related), Protocol Deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Continuing
Generated On: 27 Jul 2020 15:10:41

Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: COVID-19 Impact
Generated On: 27 Jul 2020 15:10:41

Visit	Screening ☐
	Visit 1 Day 1 ☐
	Visit 2 Day 8 ☐
	Visit 3 Day 15 ☐
	Visit 4 Day 29 ☐
	Visit 5 Day 36 ☐
	Visit 6 Day 43 ☐
	Visit 7 Day 57 ☐
	Visit 8 Day 209 ☐
	Visit 9 Day 394 ☐

Case Report Form	
Visit Date	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory	
Central Laboratory with Serology	
Central Laboratory with FSH/Serology	
Central Laboratory - Nasopharyngeal Swab	
SARS-CoV-2 or COVID-19 Exposure Assessment	
SARS-CoV-2 or COVID-19 Symptoms Assessment	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Central Laboratory - Antibody-Mediated Immunogenicity	
Safety Call	
Solicited Rash	
Lymphadenopathy	

Dosing Discontinuation	
End of Study / Study Discontinuation	
All	

Date of missed or out of window visit or assessment	
Category	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	
Visit performed out of window	
Assessment performed out of window	
Scheduled clinical visit performed as home visit	
Other	
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	
Travel restrictions	
Quarantine due to COVID-19	
Possible exposure to COVID-19	
Exposure to COVID-19	
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Temp
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any rash or underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	Fixed Unit: °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	
PC Close Date & Time	

TIMEPOINT	
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE** ?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING / HARDNESS AT INJECTION SITE**	Yes ☐ No ☐
Please record - **SWELLING / HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	
PC Close Date & Time	

TIMEPOINT	
HEADACHE	None ☐
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ☐
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ☐
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
RASH	No ☐

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	Yes ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Inj Pain
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	
PC Close Date & Time	
Hidden Check (Programming Only)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Redness
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Is there any **REDNESS AT INJECTION SITE** ?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
PC Time Stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Swelling
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Is there any **SWELLING / HARDNESS AT INJECTION SITE** ?	Yes ☐ No ☐
Please record - **SWELLING / HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Headache
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Select one response below to indicate the intensity of your **HEADACHE**	None ☐ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	
PC Close Date & Time	
Hidden Check (Programming Only)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Fatigue
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: MuscleAche
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: JointsAche
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Nausea
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Select one response below to indicate the level of your **NAUSEA/VOMITING**	None ☐ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Chills
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Select one response below to indicate the intensity of **CHILLS** you are experiencing	None ☐ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
PC Open Date & Time	
PC Close Date & Time	
PC Time stamp	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Rash
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TIMEPOINT	
Select one response below if you have **RASH**	No ☐ Yes ☐
PC Open Date & Time	
PC Close Date & Time	
PC Time Stamp	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: MedAtten
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	
Hidden Check (Programming Only)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: UnderarmGland
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date and Time	
PC Close Date and Time	
Hidden Check (Programming Only)	

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Safety Follow Up Diary
Generated On: 27 Jul 2020 15:10:41

TIMEPOINT	
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Safety Follow Up Diary
Generated On: 27 Jul 2020 15:10:41

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	
Patient Cloud Close Date & Time	