16.1.2 Sample Case Report Form (Unique Pages Only)

This section contains the following documents:

Sample case report form dated 30 Apr 2021 (Unique Pages)

Sample case report form dated 30 Apr 2021 (Cosmetic Injections and Dermal Fillers eDiary)

v13.005 Publish Checks to Prod CRF Version 1725 - Uniques

Generated By: (b) (6)

Generated On: 30 Apr 2021 19:52:48

All time stamps listed in this document are displayed in GMT

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Participant Creation
Generated On: 30 Apr 2021 19:52:48

Participant ID _____

mRNA-1273-P301 Completion Guidelines _____

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Visit Date
Generated On: 30 Apr 2021 19:52:48

Was this visit performed?	Yes ☐ No ☐
Visit date (dd MMM yyyy)	_____
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Randomization
Generated On: 30 Apr 2021 19:52:48

What was the date of randomization? *(dd MMM yyyy)*	_____
What was the participant's randomization number?	_____
In what Cohort was the participant enrolled?	>=18 and <65 years and not at risk ☐ >=18 and <65 years and at risk ☐ >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes ☐ No ☐
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes ☐ No ☐
Severe obesity (body mass index > or = 40kg/m2	Yes ☐ No ☐
Diabetes (Type I, Type 2, or gestational)	Yes ☐ No ☐
Liver Disease	Yes ☐ No ☐
Human Immunodeficiency Virus (HIV) infection	Yes ☐ No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Unblinding
Generated On: 30 Apr 2021 19:52:48

Date of updated informed consent *(dd MMM yyyy)*	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	
Was the participant unblinded?	Yes ☐ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ☐
Date of unblinding *(dd MMM yyyy)*	
Participant randomization assignment	mRNA-1273 ☐ Placebo ☐
Actual Dose 1	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Unscheduled Visit Assessment
Generated On: 30 Apr 2021 19:52:48

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Demographics
Generated On: 30 Apr 2021 19:52:48

Date of Birth (MMM yyyy)	
Age	
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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Enrollment
Generated On: 30 Apr 2021 19:52:48

Date of Informed Consent *(dd MMM yyyy)*	_____
Protocol Version	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	_____

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

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Inclusion/Exclusion Criteria
Generated On: 30 Apr 2021 19:52:48

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 ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Medical History Summary
Generated On: 30 Apr 2021 19:52:48

Were any significant conditions reported?	Yes ☐ No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Medical History
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Vital Signs
Generated On: 30 Apr 2021 19:52:48

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

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Vital Signs - Dosing
Generated On: 30 Apr 2021 19:52:48

Height	**cm** ☐ in ☐
Weight	**kg** ☐ lb ☐
BMI (xxx.x)	
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)
Temperature *(xxx.x)*	**C** ☐ F ☐
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	Fixed Unit: beats/min
Respiratory Rate *(xxx)*	Fixed Unit: breaths/min
Systolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Diastolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
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)

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Vital Signs - Dosing
Generated On: 30 Apr 2021 19:52:48

Temperature *(xxx.x)*	**C** ☐ F ☐
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	Fixed Unit: beats/min
Respiratory Rate *(xxx)*	Fixed Unit: breaths/min
Systolic Blood Pressure *(xxx)*	Fixed Unit: mmHg
Diastolic Blood Pressure *(xxx)*	Fixed Unit: mmHg

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Physical Examination
Generated On: 30 Apr 2021 19:52:48

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.

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Childbearing Potential
Generated On: 30 Apr 2021 19:52:48

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	_____

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Pregnancy Test
Generated On: 30 Apr 2021 19:52:48

Was the pregnancy test performed?	Yes ☐ No ☐
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ☐
Collection date	
Collection time	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Exposure
Generated On: 30 Apr 2021 19:52:48

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 ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	
What was the study treatment? (Unblinded)	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	Fixed Unit: (24 HR)
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?	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Immunogenicity Assessment
Generated On: 30 Apr 2021 19:52:48

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR)

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 30 Apr 2021 19:52:48

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)*	
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)*	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 30 Apr 2021 19:52:48

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00 - 23:59)*	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Safety Call
Generated On: 30 Apr 2021 19:52:48

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*	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Adverse Events Summary
Generated On: 30 Apr 2021 19:52:48

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

If Yes, enter details on the Adverse Events form.

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Adverse Events
Generated On: 30 Apr 2021 19:52:48

AEID	
Adverse event	
Was this a medically-attended AE?	Yes ☐ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☐
Start date *(dd MMM yyyy)*	
Start time *(00:00-23:59)*	Fixed Unit: (24 HR)
Ongoing?	Yes ☐ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
End time *(00:00-23:59)*	Fixed Unit: (24 HR)
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:	
Narrative	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 30 Apr 2021 19:52:48

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

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

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Prior/Concomitant Medication and Vaccination
Generated On: 30 Apr 2021 19:52:48

Name of Medication	
Prophylaxis	Yes ☐ No ☐
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 ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Concomitant Procedures Summary
Generated On: 30 Apr 2021 19:52:48

Were any concomitant procedures performed?	Yes ☐ No ☐

If yes, please complete Concomitant Procedures form.

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Concomitant Procedures
Generated On: 30 Apr 2021 19:52:48

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

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Dosing Discontinuation
Generated On: 30 Apr 2021 19:52:48

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: End of Study / Study Discontinuation
Generated On: 30 Apr 2021 19:52:48

Date of study discontinuation/completion *(dd MMM yyyy)*	
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, 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 ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Continuing
Generated On: 30 Apr 2021 19:52:48

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

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Risk of Exposure
Generated On: 30 Apr 2021 19:52:48

Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ☐
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ☐
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ☐
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ☐
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ☐
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ☐
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ☐
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ☐
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ☐
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ☐
Other	Yes ☐ No ☐
Specify	_____
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	_____
Resides in Nursing Home or Assisted Living Facility	_____
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	_____

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	
Resides in a single family home (i.e., detached housing)	
Other	
Specify	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: COVID-19 Contact
Generated On: 30 Apr 2021 19:52:48

Date of Contact	_____
Time of Contact	_____
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

Symptom Day	
	Day 1 ☐
	Day 2 ☐
	Day 3 ☐
	Day 4 ☐
	Day 5 ☐
	Day 6 ☐
	Day 7 ☐
	Day 8 ☐
	Day 9 ☐
	Day 10 ☐
	Day 11 ☐
	Day 12 ☐
	Day 13 ☐
	Day 14 ☐
	Day 15 ☐
	Day 16 ☐
	Day 17 ☐
	Day 18 ☐
	Day 19 ☐
	Day 20 ☐
	Day 21 ☐
	Day 22 ☐
	Day 23 ☐
	Day 24 ☐
	Day 25 ☐
	Day 26 ☐
	Day 27 ☐
	Day 28 ☐
	Day 29 ☐
	Day 30 ☐
	Day 31 ☐
	Day 32 ☐
	Day 33 ☐

	Day 34 ☐
	Day 35 ☐
	Day 36 ☐
	Day 37 ☐
	Day 38 ☐
	Day 39 ☐
	Day 40 ☐
Date	_____
Assessment Not Done	_____
O2 Saturation	Fixed Unit: %
	_____
Temperature	**C** ☐
	F ☐
Chills	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Cough	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Shortness of Breath	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Difficulty Breathing	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐

	Not Done ☐
Fatigue	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Muscle Aches (Myalgia)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Body Aches	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Headache	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Taste	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
New Loss of Smell	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nasal Congestion	None ☐

	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Runny Nose (Rhinorrhea)	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Nausea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Vomiting	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Diarrhea	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐
Sore Throat	None ☐
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: COVID Diagnostic Test
Generated On: 30 Apr 2021 19:52:48

Date of Visit	_____
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☐
Date of Test	_____
Type of Test Performed	Nasopharyngeal Swab ☐ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify	_____
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☐
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Saliva Collection
Generated On: 30 Apr 2021 19:52:48

Visit	Day 3 ■
	Day 5 ☐
	Day 7 ☐
	Day 9 ☐
	Day 14 ☐
	Day 21 ☐
	Day 28 ☐
Was Saliva Collected?	Yes ☐
	No ☐
	NA (COVID-19 Negative) ☐
Date of Collection	_____
Visit	Day 3 ☐
	Day 5 ■
	Day 7 ☐
	Day 9 ☐
	Day 14 ☐
	Day 21 ☐
	Day 28 ☐
Was Saliva Collected?	Yes ☐
	No ☐
	NA (COVID-19 Negative) ☐
Date of Collection	_____
Visit	Day 3 ☐
	Day 5 ☐
	Day 7 ■
	Day 9 ☐
	Day 14 ☐
	Day 21 ☐
	Day 28 ☐
Was Saliva Collected?	Yes ☐
	No ☐
	NA (COVID-19 Negative) ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Saliva Collection
Generated On: 30 Apr 2021 19:52:48

Date of Collection	_____
Visit	Day 3 ☐ Day 5 ☐ Day 7 ☐ Day 9 ■ Day 14 ☐ Day 21 ☐ Day 28 ☐
Was Saliva Collected?	Yes ☐ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	_____
Visit	Day 3 ☐ Day 5 ☐ Day 7 ☐ Day 9 ☐ Day 14 ■ Day 21 ☐ Day 28 ☐
Was Saliva Collected?	Yes ☐ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	_____
Visit	Day 3 ☐ Day 5 ☐ Day 7 ☐ Day 9 ☐ Day 14 ☐ Day 21 ■ Day 28 ☐
Was Saliva Collected?	Yes ☐ No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Saliva Collection
Generated On: 30 Apr 2021 19:52:48

	NA (COVID-19 Negative) ☐
Date of Collection	
Visit	Day 3 ☐
	Day 5 ☐
	Day 7 ☐
	Day 9 ☐
	Day 14 ☐
	Day 21 ☐
	Day 28 ■
Was Saliva Collected?	Yes ☐
	No ☐
	NA (COVID-19 Negative) ☐
Date of Collection	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection
Generated On: 30 Apr 2021 19:52:48

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?	Yes ☐ No ☐ NA (COVID-19 Negative) ☐
Date of Collection	_____

Did the subject have Respiratory Rates ≥ 30 per Minute?	Yes ☐ No ☐
If Yes, provide:	
Start Date	
End Date	
Respiratory Rate	Fixed Unit: /minute
Did the subject have Heart Rate ≥ 125 beats per minute	Yes ☐ No ☐
If Yes, provide:	
Start Date	
End Date	
Heart Rate	Fixed Unit: BPM
Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?	Yes ☐ No ☐
If Yes, provide:	
Start Date	
End Date	
Oxygen Saturation	Fixed Unit: %
Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?	Yes ☐ No ☐
If Yes, provide:	
Start Date	
End Date	
PaO2	Fixed Unit: mmHg
Did the subject have Respiratory failure?	Yes ☐ No ☐
Start Date	

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?	Yes ☐ No ☐
Start Date	
If Yes to either Did subject require any of the following:	
Ventilator Support:	
High-Flow Oxygen?	Yes ☐ No ☐
Start Date	
End Date	
Non-Invasive Ventilation?	Yes ☐ No ☐
Start Date	
End Date	
Mechanical Ventilation?	Yes ☐ No ☐
Start Date	
End Date	
ECMO?	Yes ☐ No ☐
Start Date	
End Date	
Evidence of Shock:	
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	Yes ☐ No ☐
Start Date	
End Date	
Evidence of Shock Requires Vasopressors	Yes ☐ No ☐
Start Date	
End Date	
Acute Renal Dysfunction?	Yes ☐ No ☐

Start Date	
Hepatic Dysfunction?	Yes ☐ No ☐
Start Date	
Neurologic Dysfunction?	Yes ☐ No ☐
Start Date	
Evidence of Pneumonia:	
Clinical Evidence	Yes ☐ No ☐
Date of Assessment	
Radiographical Evidence	Yes ☐ No ☐
Date of Assessment	
Admission to an intensive care unit due to SARS-CoV-2	Yes ☐ No ☐
Start Date	
End Date	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Generate Next COVID-19 Assessment
Generated On: 30 Apr 2021 19:52:48

Generate Next COVID-19 Assessment	Yes ☐ No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: COVID-19 Impact
Generated On: 30 Apr 2021 19:52:48

Visit	
	Screening ☐
	Visit 1 Day 1 ☐
	Visit 2 Day 29 ☐
	Visit 3 Day 57 ☐
	Visit 4 Day 209 ☐
	Visit 5 Day 394 ☐
	Visit 6 Day 759 ☐

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 - Nasopharyngeal Swab	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Immunogenicity Assessment	
Saliva Collection	
COVID Diagnostic Test	
Symptom Log	
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	
COVID-19 Severity Assessment	
COVID-19 Contact	
Risk of Exposure	
Safety Call	
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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Temperature_Day
Generated On: 30 Apr 2021 19:52:48

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 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 ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: General_Day
Generated On: 30 Apr 2021 19:52:48

	Yes ☐
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Injection Pain_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Redness_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Swelling_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Headache_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Fatigue_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: MuscleAche_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: JointsAche_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Nausea_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Chills_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Rash_Day
Generated On: 30 Apr 2021 19:52:48

TIMEPOINT	
Select one response below if you have **RASH**	No ☐ Yes ☐
PC Open Date & Time	
PC Close Date & Time	
PC Time Stamp	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Medical Attention_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Underarm Gland_Day
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Safety Follow Up Diary
Generated On: 30 Apr 2021 19:52:48

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 ☐

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Safety Follow Up Diary
Generated On: 30 Apr 2021 19:52:48

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	

v13.005 Publish Checks to Prod CRF Version 1725: Uniques
Folder: Uniques
Form: Safety Report Form
Generated On: 30 Apr 2021 19:52:48

SAEID	
Serious	Yes ☐ No ☐
Death	Yes ☐ No ☐
Life threatening	Yes ☐ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☐
Congenital anomaly or birth defect	Yes ☐ No ☐
Other medically important event	Yes ☐ No ☐
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	
E2B Transmit Flag (Derived/Hidden)	
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	

PRODUCTION RELEASE (v12.003 EAB) - MASTER

Generated By: Deshondon Williams Implementation Consultant

Generated On: 30 Apr 2021 20:23:29

All time stamps listed in this document are displayed in GMT

PRODUCTION RELEASE (v12.003 EAB): MASTER
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 30 Apr 2021 20:23:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Yes ☐ No ☐
Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Yes ☐ No ☐
Date & Time of Submission	_____