v5.005 SFA - Unique eCRFs

Generated By: (b) (6) Implementation Consultant

Generated On: 24 Feb 2021 00:47:22

All time stamps listed in this document are displayed in GMT

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Participant Creation
Generated On: 24 Feb 2021 00:47:22

Participant ID	
mRNA-1273-P201 Completion Guidelines	
Now	

SV = Subject Visits **SS = Subject Status**

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Visit Date
Generated On: 24 Feb 2021 00:47:22

Was this visit performed?	[NOT SUBMITTED]	Yes ☐ No ☐
Visit date (dd MMM yyyy)	SVSTDTC	SSDTC
Has participant been exposed or potentially exposed to COVID-19?	SSORRES when SSTESTCD = COVID	Yes ☐ No ☐
Is participant COVID-19 symptomatic? *Only record new symptoms since the last visit*	SSORRES when SSTESTCD = COVIDSYM	Yes ☐ No ☐
Folder OID	[NOT SUBMITTED]	

SV = Subject Visits

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Unscheduled Visit Assessment
Generated On: 24 Feb 2021 00:47:22

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

DM = Demographics

XM = Multiple participation

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Demographics
Generated On: 24 Feb 2021 00:47:22

Date of Birth (MMM yyyy)	BRTHDTC	BRTHDTC	
Age	AGE	AGE	
Age Units	AGEU	AGEU	
Age (Derived)	[NOT SUBMITTED]		
Sex	SEX	SEX	Female ☐ Male ☐
Ethnicity	ETHNIC		Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
	ETHNIC		

Race (Check All That Apply)	RACE	RACE	
White	If more than one RACE then RACE=MULTIPLE	If more than one RACE then RACE=MULTIPLE	
Black			
Asian			
American Indian or Alaska Native	SUPPDM.QVAL when QNAM = MULRACE		
Native Hawaiian or other Pacific Islander	SUPPXM.QVAL when QNAM = MULRACE		
Other			
If race is Other, specify	SUPPDM.QVAL when QNAM = RACEOTH		
Unknown	SUPPXM.QVAL when QNAM = RACEOTH		
Not reported			

DM = Demographics | DS = Disposition | XM = Multiple participation

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Enrollment
Generated On: 24 Feb 2021 00:47:22

DSCAT = PROTOCOL MILESTONE

Date of Informed Consent *(dd MMM yyyy)*	DSSTDTC when DSTERM = INFORMED CONSENT OBTAINED	RFICDTC RFICDTC
Month and Year of Informed Consent (derived)		
Year of Informed Consent (derived)		
Protocol Version	SUPPDM.QVAL when QNAM = PROTVER SUPPXM.QVAL when QNAM = PROTVER	Original ☐ Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	SUPPDS.QVAL when QNAM = ENROLLYN	Yes ☐ No ☐
If No, indicate reason for screen fail DSCAT = DISPOSITION EVENT	DSTERM	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	DSTERM	
Was this participant screened previously?	SUPPDM.QVAL when QNAM = PREVSCR SUPPXM.QVAL when QNAM = PREVSCR	Yes ☐ No ☐
If Yes, previous participant number	SUPPDM.QVAL when QNAM = PREVNUM	
Enrollment Trigger	[NOT SUBMITTED]	SUPPXM.QVAL when QNAM = PREVNUM

DM = Demographics

v5.005 SFA: Unique eCRFs

Folder: Uniques

Form: Amendment 5 Enrollment

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mRNA-1273-P301 Participant ID	SUPPDM.QVAL when QNAM = A5PREVID	
Dose Level Assigned	ARM	mRNA-1273.351 20ug ☐ mRNA-1273.351 50ug ☐ mRNA-1273 25ug + mRNA-1273.351 25ug ☐

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Inclusion/Exclusion Criteria Summary
Generated On: 24 Feb 2021 00:47:22

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

IE = Inclusion/Exclusion Criteria Not Met

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Inclusion/Exclusion Criteria
Generated On: 24 Feb 2021 00:47:22

Select inclusion criteria not met and/or exclusion criteria met

Criterion Type	IECAT = INCLUSION	Inclusion ☐
	IECAT = EXCLUSION	Exclusion ☐
Criterion Identifier	IETESTCD	1 ☐
		2 ☐
		3 ☐
IEORRES = N when IECAT = INCLUSION		4 ☐
IEORRES = Y when IECAT = EXCLUSION		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 ☐

DS = Disposition **DM = Demographics**

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Unblinding
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Did the participant consent to Part B? [NOT SUBMITTED] Yes

DSCAT = PROTOCOL MILESTONE DSSCAT = OPEN LABEL No

DSSTDTC when DSTERM = INFORMED CONSENT OBTAINED cable

Date of updated informed consent *(dd MMM yyyy)*

Was the participant unblinded? SUPPDM.QVAL when QNAM = UNBLNDYN Yes

DSSTDTC when DSTERM = TREATMENT UNBLINDED

Not Applicable

Date of unblinding *(dd MMM yyyy)*

Treatment given in Part A [NOT SUBMITTED] Placebo

mRNA-1273 50ug

SUPPDM.QVAL when QNAM = UNBLMRNA 00ug

Will participant receive mRNA-1273? Yes

No

No Dose Flag

Single Dose Flag [NOT SUBMITTED]

Double Dose Flag

Continuing with mRNA-1273

OL-D29 Dose Post Matrix Merge Flag

OL-D29 Dose Post Matrix Merge Flag

OL-D57 Flag

Safety Call OL-D85 Flag

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Medical History Summary
Generated On: 24 Feb 2021 00:47:22

Were any significant conditions reported??	Yes ☐
	No ☐

MH = Medical History

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Medical History
Generated On: 24 Feb 2021 00:47:22

Condition	MHTERM	
Start date (dd MMM yyyy)	MHSTDTC	
Start date completely unknown	[NOT SUBMITTED]	
Condition ongoing at study entry	MHENRTPT	Yes ☐ No ☐
If No, please specify the stop date (dd MMM yyyy)	MHENDTC	
Stop date completely unknown	[NOT SUBMITTED]	
Start Month and Year (derived)	[NOT SUBMITTED]	
Start Year (derived)	[NOT SUBMITTED]	
Stop Month and Year (derived)	[NOT SUBMITTED]	
Stop Year (derived)	[NOT SUBMITTED]	

VS = Vital Signs

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Vital Signs
Generated On: 24 Feb 2021 00:47:22

Were vital signs assessed? Yes / No
VSSTAT = NOT DONE

Date of assessment *(dd MMM yyyy)*: VSDTC

Time of assessment *(00:00-23:59)*: VSDTC — Fixed Unit: (24 HR)

Vital Signs Date and Time (derived): [NOT SUBMITTED]

Height *(xxx.x)*: VSTEST = Height; VSORRES / VSORRESU when VSTESTCD = HEIGHT — cm / in

Weight *(xxx.x)*: VSTEST = Weight; VSORRES / VSORRESU when VSTESTCD = WEIGHT — kg / lb

BMI *(xxx.x)*: VSTEST = Body Mass Index; VSORRES / VSORRESU when VSTESTCD = BMI — Fixed Unit: kg/m^2

BMI units

Temperature *(xxx.x)*: VSTEST = Temperature; VSORRES / VSORRESU when VSTESTCD = TEMP — C / F

Route of measurement: VSLOC — Oral / Axillary / Other

If Other, specify: SUPPVS.QVAL when QNAM = VSLOCSP

Pulse *(xxx)*: VSTEST = Pulse Rate; VSORRES / VSORRESU when VSTESTCD = PULSE — Fixed Unit: beats/min

Pulse units

Respiratory Rate *(xxx)*: VSTEST = Respiratory Rate; VSORRES / VSORRESU when VSTESTCD = RESP — Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure *(xxx)*: VSTEST = Systolic Blood Pressure; VSORRES / VSORRESU when VSTESTCD = SYSBP — Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure *(xxx)*: VSTEST = Diastolic Blood Pressure; VSORRES / VSORRESU when VSTESTCD = DIABP — Fixed Unit: mmHg

Diastolic Blood Pressure units

VS = Vital Signs

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Vital Signs - Dosing
Generated On: 24 Feb 2021 00:47:22

Height — VSTEST = Height — VSORRES / VSORRESU when VSTESTCD = HEIGHT — cm / in

Weight — VSTEST = Weight — VSORRES / VSORRESU when VSTESTCD = WEIGHT — kg / lb

BMI *(xxx.x)* — VSTEST = Body Mass Index — VSORRES / VSORRESU when VSTESTCD = BMI — Fixed Unit: kg/m^2

BMI units

Timepoint — VSTPT — Pre-Dose / Post-Dose

Were vital signs assessed? — VSSTAT = NOT DONE — Yes / No

Date of assessment *(dd MMM yyyy)* — VSDTC

Time of assessment *(00:00-23:59)* — VSDTC — Fixed Unit: (24 HR)

Vital Signs Date and Time (derived) — [NOT SUBMITTED]

Temperature *(xxx.x)* — VSTEST = Temperature — VSORRES / VSORRESU when VSTESTCD = TEMP — C / F

Route of measurement — VSLOC — Oral / Axillary / Other

If Other, specify — SUPPVS.QVAL when QNAM = VSLOCSP

Pulse *(xxx)* — VSTEST = Pulse Rate — Fixed Unit: beats/min

Pulse units — VSORRES / VSORRESU when VSTESTCD = PULSE

Respiratory Rate *(xxx)* — VSTEST = Respiratory Rate — Fixed Unit: breaths/min

Respiratory Rate units — VSORRES / VSORRESU when VSTESTCD = RESP

Systolic Blood Pressure *(xxx)* — VSTEST = Systolic Blood Pressure — Fixed Unit: mmHg

Systolic Blood Pressure units — VSORRES / VSORRESU when VSTESTCD = SYSBP

Diastolic Blood Pressure *(xxx)* — VSTEST = Diastolic Blood Pressure — Fixed Unit: mmHg

VSORRES / VSORRESU when VSTESTCD = DIABP

VS = Vital Signs

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Vital Signs - Dosing
Generated On: 24 Feb 2021 00:47:22

Diastolic Blood Pressure units — VSORRES / VSORRESU when VSTESTCD = DIABP

Timepoint — VSTPT — Pre-Dose ☐ Post-Dose ■

Were vital signs assessed? — Yes ☐ No ☐ — VSSTAT = NOT DONE

Date of assessment *(dd MMM yyyy)* — VSDTC

Time of assessment *(00:00-23:59)* — VSDTC — Fixed Unit: (24 HR)

Vital Signs Date and Time (derived) — [NOT SUBMITTED]

Temperature *(xxx.x)* — VSTEST = Temperature — VSORRES / VSORRESU when VSTESTCD = TEMP — C ☐ F ☐

Route of measurement — VSLOC — Oral ☐ Axillary ☐ Other ☐

If Other, specify — SUPPVS.QVAL when QNAM = VSLOCSP

Pulse *(xxx)* — VSTEST = Pulse Rate — Fixed Unit: beats/min

Pulse units — VSORRES / VSORRESU when VSTESTCD = PULSE

Respiratory Rate *(xxx)* — VSTEST = Respiratory Rate — Fixed Unit: breaths/min

Respiratory Rate units — VSORRES / VSORRESU when VSTESTCD = RESP

Systolic Blood Pressure *(xxx)* — VSTEST = Systolic Blood Pressure — Fixed Unit: mmHg

Systolic Blood Pressure units — VSORRES / VSORRESU when VSTESTCD = SYSBP

Diastolic Blood Pressure *(xxx)* — VSTEST = Diastolic Blood Pressure — Fixed Unit: mmHg

Diastolic Blood Pressure units — VSORRES / VSORRESU when VSTESTCD = DIABP

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Physical Examination
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Was the physical examination performed? **FAOBJ** Yes ☐

FAORRES when FATESTCD = ASSESS No ☐

Date of examination *(dd MMM yyyy)* **FADTC**

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

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory
Generated On: 24 Feb 2021 00:47:22

Collection date *(dd MMM yyyy)* — LBDTC

Lab panel — LBCAT
- Hematology ■
- Chemistry ☐
- Serology ☐
- Coagulation ☐

Was the sample collected? — LBSTAT = NOT DONE
- Yes ☐
- No ☐

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ☐
- Chemistry ■
- Serology ☐
- Coagulation ☐

Was the sample collected? — LBSTAT = NOT DONE
- Yes ☐
- No ☐

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ☐
- Chemistry ☐
- Serology ☐
- Coagulation ■

Was the sample collected? — LBSTAT = NOT DONE
- Yes ☐
- No ☐

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory with Serology
Generated On: 24 Feb 2021 00:47:22

Collection date *(dd MMM yyyy)* — LBDTC

Lab panel — LBCAT
- Hematology ●
- Chemistry ☐
- Serology ☐
- Coagulation ☐

Was the sample collected?
- Yes ☐
- No ☐ — LBSTAT = NOT DONE

Collection time *(00:00-23:59)* — Fixed Unit: (24 HR) — LBDTC

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ☐
- Chemistry ●
- Serology ☐
- Coagulation ☐

Was the sample collected?
- Yes ☐
- No ☐ — LBSTAT = NOT DONE

Collection time *(00:00-23:59)* — Fixed Unit: (24 HR) — LBDTC

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ☐
- Chemistry ☐
- Serology ●
- Coagulation ☐

Was the sample collected?
- Yes ☐
- No ☐ — LBSTAT = NOT DONE

Collection time *(00:00-23:59)* — Fixed Unit: (24 HR) — LBDTC

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ☐
- Chemistry ☐
- Serology ☐

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory with Serology
Generated On: 24 Feb 2021 00:47:22

	LBCAT	Coagulation
Was the sample collected?		Yes ☐
	LBSTAT = NOT DONE	No ☐
Collection time *(00:00-23:59)*		Fixed Unit: (24 HR)
	LBDTC	
Collection date and time (derived)	[NOT SUBMITTED]	

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory with FSH/Serology
Generated On: 24 Feb 2021 00:47:22

Collection date *(dd MMM yyyy)* — LBDTC

Lab panel — LBCAT
- Hematology ●
- Chemistry ○
- Serology ○
- Coagulation ○
- FSH ○

Was the sample collected?
- Yes ○
- No ○ — LBSTAT = NOT DONE

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ○
- Chemistry ●
- Serology ○
- Coagulation ○
- FSH ○

Was the sample collected?
- Yes ○
- No ○ — LBSTAT = NOT DONE

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ○
- Chemistry ○
- Serology ●
- Coagulation ○
- FSH ○

Was the sample collected?
- Yes ○
- No ○ — LBSTAT = NOT DONE

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory with FSH/Serology
Generated On: 24 Feb 2021 00:47:22

Lab panel — LBCAT
- Hematology ☐
- Chemistry ☐
- Serology ☐
- Coagulation ■
- FSH ☐

Was the sample collected? — LBSTAT = NOT DONE
- Yes ☐
- No ☐

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

Lab panel — LBCAT
- Hematology ☐
- Chemistry ☐
- Serology ☐
- Coagulation ☐
- FSH ■

Was the sample collected? — LBSTAT = NOT DONE
- Yes ☐
- No ☐

Collection time *(00:00-23:59)* — LBDTC — Fixed Unit: (24 HR)

Collection date and time (derived) — [NOT SUBMITTED]

MB = Microbiology Specimen

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 24 Feb 2021 00:47:22

MBCAT = SARS-CoV-2 for COVID-19 test
MBCAT = BIOFIRE for Biofire RP Panel

Collection date *(dd MMM yyyy)* — MBDTC

Lab Test — MBSCAT

- Nasopharyngeal Swab 1 ●
- Nasopharyngeal Swab 2 ○
- Blood Collection for exposure to SARS-CoV-2 ○

Was the sample collected?

- Yes ○
- No ○

MBSTAT = NOT DONE

Collection time *(00:00 - 23:59)* — MBDTC

Collection date and time (derived) — [NOT SUBMITTED]

Lab Test — MBSCAT

- Nasopharyngeal Swab 1 ○
- Nasopharyngeal Swab 2 ●
- Blood Collection for exposure to SARS-CoV-2 ○

Was the sample collected?

- Yes ○
- No ○

MBSTAT = NOT DONE

Collection time *(00:00 - 23:59)* — MBDTC

Collection date and time (derived) — [NOT SUBMITTED]

MB = Microbiology Specimen

MBCAT = SARS-CoV-2 for COVID-19 test
MBCAT = BIOFIRE for Biofire RP Panel

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Nasopharyngeal Swab and Blood Collection for SARS-CoV-2
Generated On: 24 Feb 2021 00:47:22

Collection date *(dd MMM yyyy)* — **MBDTC**

Lab Test — **MBSCAT**
- Nasopharyngeal Swab 1 ■
- Nasopharyngeal Swab 2 ☐
- Blood Collection for exposure to SARS-CoV-2 ☐

Was the sample collected?
- Yes ☐
- No ☐ — **MBSTAT = NOT DONE**

Collection time *(00:00 - 23:59)* — **MBDTC**

Collection date and time (derived) — **[NOT SUBMITTED]**

Lab Test — **MBSCAT**
- Nasopharyngeal Swab 1 ☐
- Nasopharyngeal Swab 2 ■
- Blood Collection for exposure to SARS-CoV-2 ☐

Was the sample collected?
- Yes ☐
- No ☐ — **MBSTAT = NOT DONE**

Collection time *(00:00 - 23:59)* — **MBDTC**

Collection date and time (derived) — **[NOT SUBMITTED]**

Lab Test — **MBSCAT**
- Nasopharyngeal Swab 1 ☐
- Nasopharyngeal Swab 2 ☐
- Blood Collection for exposure to SARS-CoV-2 ■

Was the sample collected?
- Yes ☐
- No ☐ — **MBSTAT = NOT DONE**

Collection time *(00:00 - 23:59)* — **MBDTC**

Collection date and time (derived) — **[NOT SUBMITTED]**

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Unscheduled
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Collection date *(dd MMM yyyy)*	LBDTC
Lab panel	LBCAT Hematology ☐ Chemistry ☐ Coagulation ☐ Other ☐
If Other, specify	SUPPLB.QVAL when QNAM=PANELOTH
Collection time *(00:00-23:59)*	Fixed Unit: (24 HR) LBDTC
Collection date and time (derived)	[NOT SUBMITTED]

RP = Reproductive System Findings

v5.005 SFA: Unique eCRFs

Folder: Uniques

Form: Childbearing Potential

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Date of assessment *(dd MMM yyyy)*	RPDTC	
Is the participant of childbearing potential?	RPORRES when RPTESTCD = CHILDPOT	Yes ☐ No ☐
If No, what is the reason?	SUPPRP.QVAL when QNAM=CBRSN	Surgically sterile ☐ Post-menopausal ☐ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	SUPPRP.QVAL when QNAM=CBSP	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	SUPPRP.QVAL when QNAM=CBSDTC	
Date of surgery unknown	SUPPRP.QVAL when QNAM=CBSDAUNK	
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	SUPPRP.QVAL when QNAM=CBENDTC	
Date of last menstruation unknown	SUPPRP.QVAL when QNAM=CBENDUNK	

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Pregnancy Test
Generated On: 24 Feb 2021 00:47:22

Was the pregnancy test performed?	LBCAT = PREGNANCY TEST	LBSTAT = NOT DONE	Yes ☐ No ☐
Date of test *(dd MMM yyyy)*		LBDTC	
Test performed		LBSPEC	Urine ☐ Serum ☐
Result	LBORRES when LBTESTCD = HCG		Positive ☐ Negative ☐

DM = Demographics | DS = Disposition

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Randomization
Generated On: 24 Feb 2021 00:47:22

DSCAT = PROTOCOL MILESTONE

DSTERM = RANDOMIZED

What was the date of randomization? *(dd MMM yyyy)* DSSTDTC

What was the participant's randomization number? DSREFID

In what Cohort was the participant enrolled?

SUPPDM.QVAL when QNAM = COHORT

- ☐ Cohort 1: Age >= 18 to < 55 mRNA-1273 or Placebo
- ☐ Cohort 2: Age >= 55 mRNA-1273 or Placebo

Was this a Sentinel participant?

SUPPDM.QVAL when QNAM = SENTL

- ☐ Yes
- ☐ No

EC = Exposure as Collected | EX = Exposure | DS = Disposition

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Exposure
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DSCAT = DISPOSITION EVENT
DSSCAT = STUDY TREATMENT

ECPRESP = Y

Was study treatment given?

ECOCCUR = Y — Yes ☐
ECOCCUR = N — No ☐

DSTERM / DSDECOD = COMPLETED when Visit= Visit 4 Day 29 and Treatment given=Yes,
or when Visit= Participant Decision Visit / OL-D1 and Treatment given=Yes and subject receive mRNA in PART A
or when Visit= OL-D29 and Treatment given=Yes and subject receive Placebo in PART A

Participant declined due to Adverse Event ☐
ician withheld dose due to Adverse Event ☐
Death ☐

ECREASOC

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 — ECREASOC

What was the study treatment? — [NOT SUBMITTED]

What was the study treatment? (Unblinded)

What was the treatment date? *(dd MMM yyyy)* — EXSTDTC | ECSTDTC | DSSTDTC

What was the treatment time? *(00:00-23:59)* — EXSTDTC | ECSTDTC — Fixed Unit: (24 HR)

Treatment Date and Time (derived) — [NOT SUBMITTED]

Which arm was used to give treatment? — EXLOC | ECLOC — Left Arm ☐
EXLAT | ECLAT — Right Arm ☐

What was the frequency of the study treatment dosing? — EXDOSFRQ | ECDOSFRQ

What was the route of administration for the study treatment? — EXROUTE | ECROUTE

LB = Laboratory Test Results

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Serology LBCAT
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Was the sample collected?	LBSTAT = NOT DONE	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	LBDTC	
Collection time *(00:00-23:59)*	LBDTC	Fixed Unit: (24 HR)
Collection date and time (derived)	[NOT SUBMITTED]	

IS = Immunogenicity Specimen Assessments

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Antibody-Mediated Immunogenicity
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Lab panel	ISCAT	Antibody-mediated Immunogenicity
Was the sample collected?	ISSTAT = NOT DONE	Yes / No
Collection date *(dd MMM yyyy)*	ISDTC	
Collection time *(00:00-23:59)*	ISDTC	Fixed Unit: (24 HR)
Collection date and time (derived)	[NOT SUBMITTED]	

SS = Subject Status **SV = Subject Visits**

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Safety Call **SSCAT = SAFETY CALL**
Generated On: 24 Feb 2021 00:47:22

Was Contact Attempted? **SSORRES when SSTESTCD = CONTACT** Yes ☐ No ☐

Date of Contact or Contact Attempt *(dd MMM yyyy)* **SSDTC** **SVSTDTC**

Please select one status for the follow-up contact Contact Made ☐
SSORRES when SSTESTCD = CONSTAT Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments **SUPPSS.QVAL when QNAM = SCREAS**

Has participant been exposed or potentially exposed to COVID-19? Yes ☐
SSORRES when SSTESTCD = COVID No ☐

Is participant COVID-19 symptomatic? Yes ☐
SSORRES when SSTESTCD = COVIDSYM No ☐

Only record new symptoms since the last visit

ER = Environmental and Social Factors

v5.005 SFA: Unique eCRFs
Folder: Uniques ERCAT = COVID-19 EXPOSURE
Form: SARS-CoV-2 or COVID-19 Exposure Assessment
Generated On: 24 Feb 2021 00:47:22

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

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

Social setting	
Family member	EROCCUR
Health Care Facility	ERTERM
Work	
Travel	
Other	
Other, specify	SUPPER.QVAL when QNAM= EXPOSEOT
Estimated start date of exposure	ERSTDTC
Estimated length of exposure (in days)	Fixed Unit: days
	ERDUR
Estimated length of exposure units	

FA = Findings About

v5.005 SFA: Unique eCRFs

Folder: Uniques

Form: SARS-CoV-2 or COVID-19 Symptoms Assessment

FACAT = COVID-19 SYMPTOMS

Does the participant have symptoms of potential COVID-19?	Yes ☐
FAOBJ = COVID-19 **FAORRES when FATESTCD = OCCUR**	No ☐
Estimated date of first symptoms **SUPPFA.QVAL when QNAM= SYMPTDTC**	

(If Yes, check all symptoms that apply)

FAOBJ **FACAT = COVID-19 SYMPTOMS**

Only record new symptoms since the last visit	
Cough	
Shortness of Breath **FAORRES when FATESTCD = OCCUR**	
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 **SUPPFA.QVAL when QNAM= SYMPOTH**

FA = Findings About | CE = Clinical Events | CO = Comments

v5.005 SFA: Unique eCRFs CECAT = REACTOGENICITY
Folder: Uniques CETERM | CEPRESP = Y | FAOBJ | FACAT = REACTOGENICITY
Form: Solicited Rash
Generated On: 24 Feb 2021 00:47:22 CELNKGRP = 1010/2010/3010/4010 | FALNKGRP = 1010/2010/3010/4010

Vaccination Dose — CETPTREF | FATPTREF
- Dose 1 ☐
- Dose 2 ☐

Days Relative to Vaccination — FATPT
- 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? SUPPFA.QVAL when QNAM = SREVL
- Yes ☐
- No ☐

CESTAT = NOT DONE | FASTAT= NOT DONE

If Yes, Investigator Site or Other Institution

Investigator Site	SUPPFA.QVAL when QNAM = SITE1
Other Institution	SUPPFA.QVAL when QNAM = SITE2

Date of rash assessment by site investigator *(dd MMM yyyy)* — FADTC

Rash Location — FALOC

What is the site investigator's assessment of the rash? — CEOCCUR = N | CEOCCUR = Y

FAORRES when FATESTCD = SEV

- 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 — COVAL | COREF = SRCOMM

FA = Findings About | CE = Clinical Events | CO = Comments

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Lymphadenopathy
Generated On: 24 Feb 2021 00:47:22

CECAT = REACTOGENICITY
CETERM | CEPRESP = Y | FAOBJ | FACAT = REACTOGENICITY
CELNKGRP = 1020/2020/3020/4020
FALNKGRP = 1020/2020/3020/4020

Vaccination Dose — CETPTREF | FATPTREF

- Dose 1 ☐
- Dose 2 ☐

Days Relative to Vaccination — FATPT

- 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 — SUPPFA.QVAL when QNAM = LYMPHEVL — Yes ☐ / No ☐
CESTAT = NOT DONE | FASTAT= NOT DONE

If Yes, Investigator Site or Other Institution

Investigator Site	SUPPFA.QVAL when QNAM = SITE1
Other Institution	SUPPFA.QVAL when QNAM = SITE2

Date of lymphadenopathy assessment by site investigator *(dd MMM yyyy)* — FADTC

Lymphadenopathy confirmed on physical exam? — Yes ☐ / No ☐
FAORRES when FATESTCD = OCCUR
CEOCCUR = Y | CEOCCUR = N

Additional relevant information — COVAL | COREF = LYMPHCOM

MB = Microbiology Specimen

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Local Diagnostic Test
Generated On: 24 Feb 2021 00:47:22

Date of Test	MBDTC	
Institution Name	MBNAM	
Diagnostic Test Performed	MBSPEC	Nasopharyngeal Swab ☐ Blood Test ☐ Other ☐
Other, Specify	SUPPMB.QVAL when QNAM=LDTSTOTH	
Type of Diagnostic Test (if known):	SUPPMB.QVAL when QNAM=LDTTYPE	
COVID-19 Result	MBORRES	Positive ☐ Negative ☐

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 24 Feb 2021 00:47:22

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

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

CM = Concomitant and Prior Medications

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Prior/Concomitant Medication and Vaccination
Generated On: 24 Feb 2021 00:47:22

Name of Medication	CMTRT	
Indication	CMINDC	
Dose per administration	CMDOSE	CMDOSTXT
Dose unit	CMDOSU	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	SUPPCM.QVAL when QNAM = CMUOTHSP	
Frequency	CMDOSFRQ	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	SUPPCM.QVAL when QNAM = CMFOTHSP	
Route of administration	CMROUTE	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐

CM = Concomitant and Prior Medications

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Prior/Concomitant Medication and Vaccination
Generated On: 24 Feb 2021 00:47:22

	CMROUTE	Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	SUPPCM.QVAL when QNAM = CMROTHSP	
Start date *(dd MMM yyyy)*	CMSTDTC	
Start date completely unknown	SUPPCM.QVAL when QNAM = CMSTUNKC	
Ongoing?	SUPPCM.QVAL when QNAM = CMONGOYN	Yes ☐ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	CMENDTC	
Was this medication taken for solicited event?	SUPPCM.QVAL when QNAM = CMSOL	Yes ☐ No ☐

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Concomitant Procedures Summary
Generated On: 24 Feb 2021 00:47:22

Were any concomitant procedures performed?	Yes ☐
	No ☐

If yes, please complete Concomitant Procedures form.

PR = Procedures

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Concomitant Procedures
Generated On: 24 Feb 2021 00:47:22

Procedure/Surgery date *(dd MMM yyyy)*	PRSTDTC	
Procedure/Surgery	PRTRT	
Indication	PRINDC	Adverse Event ☐ Medical History ☐ Diagnostic ☐ Other ☐
If indication is Other, specify	SUPPPR.QVAL when QNAM = PRINDOTH	

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Adverse Events Summary
Generated On: 24 Feb 2021 00:47:22

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

If Yes, enter details on the Adverse Events form.

Note: Solicited AEs' are mapped to AE only when AESER=Y or AE is beyond 7 days of dosing reference. Other solicited AE's will be flagged to be removed

Note: Solicited AE's are mapped to CE and FACE, if within 7 day window, or else mapped to FAAE

AE = Adverse Events | **HO= Healthcare Encounters** | **FA = Findings About** | **CE = Clinical Events**

Notes: --SPID will be used to link records

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Adverse Events
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY

Adverse event		AETERM / CETERM / FAOBJ	
Was this a medically-attended AE?	AESCAT = PIMMC when Yes SUPPFA.QVAL when QNAM = MAAEFL SUPPAE.QVAL when QNAM = AEMAFL		Yes ☐ No ☐
Was this a Solicited Adverse Reaction?	AECAT = REACTOGENICITY when Yes SUPPAE.QVAL when QNAM = AESOFL		Yes ☐ No ☐
Start date *(dd MMM yyyy)*	FADTC	AESTDTC	
Start time *(00:00-23:59)*	FADTC	AESTDTC	Fixed Unit: (24 HR)
AE start date and time (derived)		[NOT SUBMITTED]	
Ongoing?		AEENRF	Yes ☐ No ☐
If not Ongoing, end date *(dd MMM yyyy)*		AEENDTC	FADTC
End time *(00:00-23:59)*		AEENDTC	Fixed Unit: (24 HR) FADTC
AE End Date and Time (derived)		[NOT SUBMITTED]	
Severity	FAORRES when FATESTCD = SEV SUPPCE.QVAL when QNAM = AESEVX	AETOXGR AESEV	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?		AESER	Yes ☐ No ☐
AE is serious due To (check all that apply)			
Death		AESDTH	
Life threatening		AESLIFE	
Requires inpatient or prolongation of existing Hospitalization		AESHOSP	HOTERM / HODECOD = HOSPITAL
Hospital Admission Date *(dd MMM yyyy)*		HOSTDTC	
Hospital Discharge Date *(dd MMM yyyy)*		HOENDTC	
Admitted to ICU? HOTERM HODECOD = ICU		HOOCCUR	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	HODUR		
Persistent or significant disability or incapacity		AESDISAB	
Congenital anomaly or birth defect		AESCONG	

AE = Adverse Events

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Adverse Events
Generated On: 24 Feb 2021 00:47:22

Other medically important event	AESMIE	
Relationship to investigational product	AEREL	Not Related ☐ Related ☐ Not Applicable ☐
Relationship to Study Procedure	AERELNST	Not Related ☐ Related ☐ Not Applicable ☐
Action taken with investigational product	AEACN	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)		
None		
Concomitant Medication	AEACNOTH	
Concomitant Procedure		
Outcome	AEOUT	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:	SUPPAE.QVAL when QNAM = AEOUTSP	
Enter Narrative ONLY for Serious Adverse Events		
SAE Narrative	[NOT SUBMITTED]	

DS = Disposition

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Dosing Discontinuation
Generated On: 24 Feb 2021 00:47:22

DSCAT = DISPOSITION EVENT

DSSCAT = STUDY TREATMENT

Date of dosing discontinuation (dd MMM yyyy) — **DSSTDTC**

Primary reason for dosing discontinuation — **DSTERM** / **DSDECOD**

- ☐ 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

SUPPDS.QVAL when QNAM = EOTREAS for subjects that completed planned doses and discontinued from future treatment (DSCAT=STUDY TREATMENT and DSTERM=COMPLETED. Other information on the page are not mapped for those records.

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 — **DSTERM for reason listed above**

DSSPID if DSTERM = Adverse Event (Other) or Adverse Event (COVID-19) as concatenation of AE Log line number

DS = Disposition | DD = Deaths Details | DM = Demographics

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: End of Study / Study Discontinuation
Generated On: 24 Feb 2021 00:47:22

DSCAT = DISPOSITION EVENT
DSSCAT = END OF STUDY

Date of study discontinuation/completion *(dd MMM yyyy)* DSSTDTC

Reason for discontinuation
DSTERM
DSDECOD
DSTERM = COMPLETED

- 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
DSTERM for reason listed above
DSSPID if DSTERM = Adverse Event (Other) or Adverse Event (COVID-19), as concatenation of AE Log line number

If reason for discontinuation is Death, main cause of death
DSTERM when death
DDORRES where DDTESTCD= PRCDTH

- Adverse event
- Unknown
- Other

If main cause of death is Other, specify DSTERM when death

Date of death *(dd MMM yyyy)* DDDTC
DTHDTC and DTHFL = Y

Was autopsy performed?
DDORRES where DDTESTCD= AUTOPIND

- Yes
- No
- Unknown

[NOT SUBMITTED]

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Continuing
Generated On: 24 Feb 2021 00:47:22

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

VE= VISIT EVENTS

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: COVID-19 Impact
Generated On: 24 Feb 2021 00:47:22

Visit		
		Screening ☐
		Visit 1 Day 1 ☐
	VISIT	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 ☐
		Participant Decision Visit / OL-D1 ☐
		OL-D8 ☐
		OL-D15 ☐
		OL-D29 ☐
		OL-D57 ☐
		OL-D181 ☐
		OL-D209 ☐

Case Report Form		
Visit Date		
Demographics		
Enrollment		
Inclusion/Exclusion Criteria Summary		
Inclusion/Exclusion Criteria		
Medical History Summary		
Medical History	SUPPVE.QVAL when QNAM = MISSASS	
Vital Signs	Concatenate all impacted assessment	
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		

VE= VISIT EVENTS

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: COVID-19 Impact
Generated On: 24 Feb 2021 00:47:22

Childbearing Potential	
Pregnancy Test	SUPPVE.QVAL when QNAM = MISSASS
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	VESTDTC
Category	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	VEDECOD
Visit performed out of window	
Assessment performed out of window	VETERM
Scheduled clinical visit performed as home visit	
Other	
Other, specify	VETERM
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	VEREASOC
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

VS = Vital Signs | CE = Clinical Events

Note: Mapped to CE, if within 7 day window

VSCAT = REACTOGENICITY | CECAT = REACTOGENICITY

VSSCAT = SYSTEMIC | CESCAT = SYSTEMIC

VSLNKGRP= 1150/2150/3150/4150 | CEPRESP = Y | CELNKGRP = 1150/2150/3150/4150

Form: Temp

Generated On: 24

TIMEPOINT VSTPT

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 ☐

VSSTAT = NOT DONE
Missing records will also be considered as NOT DONE

Please record your **TEMPERATURE in °F** Unit: °F

VSTEST = Temperature | VSORRES / VSORRESU when VSTESTCD = TEMP | CETERM = Fever

Was any **MEDICATION TAKEN today for pain or fever**? Yes ☐ No ☐

SUPPVS.QVAL when QNAM = MEDTAK

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred — SUPPVS.QVAL when QNAM = MEDTAKT

To **PREVENT** pain or fever from occurring — SUPPVS.QVAL when QNAM = MEDTAKP

PC Time Stamp — VSDTC

PC Open Date & Time — [NOT SUBMITTED]

PC Close Date & Time — [NOT SUBMITTED]

Notes: eDiary forms within 7 days period will be mapped to FACE. CEOCCUR is from maximum severity in the first 7 days, "Y" if there is at least one event occurred during observed period, "N" if no events and null if missing diary.

CE = Clinical Events **FA = Findings About**

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Inj Site
Generated On: 24 Feb 2021 00:47:22

CECAT = REACTOGENICITY
CESCAT = ADMINISTRATION SITE
FACAT = REACTOGENICITY
FASCAT = ADMINISTRATION SITE

TIMEPOINT CEPRESP = Y FATPT

Please record - **PAIN AT INJECTION SITE.** FAOBJ = Pain CEOCCUR = N None
Please select one response below
CETERM=Pain
Does not interfere with activity
FAORRES when FATESTCD = SEV
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
CELNKGRP = 1030/2030/3030/4030
FALNKGRP = 1030/2030/3030/4030
CEOCCUR = Y
Any use of prescription pain reliever or prevents daily activity

Is there any **REDNESS AT INJECTION SITE** ? CEOCCUR = Y Yes
CETERM = Erythema
FAORRES when FATESTCD = OCCUR
FAOBJ = Erythema
CEOCCUR = N No

Please record - **REDNESS AT INJECTION SITE (in mm)** FAORRESU FAOBJ CELNKGRP = 1040/2040/3040/4040
Measure the largest size across any injection site redness with the ruler provided.
FAORRES when FATESTCD = LDIAM
FALNKGRP = 1040/2040/3040/4040

Is there any **SWELLING / HARDNESS AT INJECTION SITE** CEOCCUR = Y Yes
FAOBJ CETERM FAORRES when FATESTCD = OCCUR
CEOCCUR = N No

Please record - **SWELLING / HARDNESS AT INJECTION SITE (in mm)** FAOBJ FAORRESU CELNKGRP = 1050/2050/3050/4050
Measure the largest size across any injection site swelling/hardness with the ruler provided.
FAORRES when FATESTCD = LDIAM
FALNKGRP = 1050/2050/3050/4050

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** FAOBJ CETERM CEOCCUR = N None
Please select one response below
Does not interfere with activity
FAORRES when FATESTCD = SEV
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
CELNKGRP = 1060/2060/3060/4060
CEOCCUR = Y
Any use of prescription pain reliever or prevents daily activity
FALNKGRP = 1060/2060/3060/4060

FADTC
PC Open Date & Time [NOT SUBMITTED]
PC Close Date & Time [NOT SUBMITTED]

Notes: eDiary forms within 7 days period will be mapped to FACE. CEOCCUR is from maximum severity in the first 7 days, "Y" if there is at least one event occurred during observed period, "N" if no events and null if missing diary.

CE = Clinical Events **FA = Findings About**

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: General
Generated On: 24 Feb 2021 00:47:22

CECAT = REACTOGENICITY
CESCAT = SYSTEMIC
FACAT = REACTOGENICITY
FASCAT = SYSTEMIC

TIMEPOINT CEPRESP = Y FATPT

HEADACHE
CELNKGRP = 1070/2070/3070/4070
FALNKGRP = 1070/2070/3070/4070
FAOBJ CETERM
FAORRES when FATESTCD = SEV
CEOCCUR = Y
CEOCCUR = N
- 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
CELNKGRP = 1080/2080/3080/4080
FALNKGRP = 1080/2080/3080/4080
FAOBJ CETERM
FAORRES when FATESTCD = SEV
CEOCCUR = Y
CEOCCUR = N
- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY CETERM = Myalgia
CELNKGRP = 1090/2090/3090/4090
FALNKGRP = 1090/2090/3090/4090
FAOBJ = Myalgia
FAORRES when FATESTCD = SEV
CEOCCUR = Y
CEOCCUR = N
- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS
CELNKGRP= 1100/2100/3100/4100
FALNKGRP = 1100/2100/3100/4100
FAOBJ = Arthralgia
CETERM = Arthralgia
FAORRES when FATESTCD = SEV
CEOCCUR = Y
CEOCCUR = N
- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING FAOBJ CETERM
CELNKGRP = 1110/2110/3110/4110
FALNKGRP = 1110/2110/3110/4110
FAORRES when FATESTCD = SEV
CEOCCUR = Y
CEOCCUR = N
- 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 FAOBJ CETERM
CELNKGRP = 1120/2120/3120/4120
FALNKGRP = 1120/2120/3120/4120
FAORRES when FATESTCD = SEV
CEOCCUR = Y
CEOCCUR = N
- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

RASH FAOBJ CETERM
FALNKGRP = 1130/2130/3130/4130
CELNKGRP = 1130/2130/3130/4130
FAORRES when FATESTCD = OCCUR
CEOCCUR = N
- No

CE = Clinical Events | FA = Findings About | HO= Healthcare Encounters

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: General
Generated On: 24 Feb 2021 00:47:22 HODECOD = MAAE | HOPRESP = Y

HOTERM = MEDICAL ATTENDED

	Yes ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐
SUPPCE.QVAL when QNAM= MAAEFL / SUPPFA.QVAL when QNAM= MAAEFL	Yes ☐ HOOCCUR =Y
PC Time stamp	HOSTDTC / HOENDTC
PC Open Date & Time	[NOT SUBMITTED]
PC Close Date & Time	[NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Inj Pain
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = ADMINISTRATION SITE
FALNKGRP = 1030/2030/3030/4030

TIMEPOINT	FATPT

Please record - **PAIN AT INJECTION SITE.** FAOBJ
Please select one response below

FAORRES when FATESTCD = SEV

- 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	FADTC
PC Open Date & Time	[NOT SUBMITTED]
PC Close Date & Time	[NOT SUBMITTED]
Hidden Check (Programming Only)	[NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Redness
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = ADMINISTRATION SITE
FALNKGRP = 1040/2040/3040/4040

TIMEPOINT FAOBJ = Erythema FATPT

Is there any **REDNESS AT INJECTION SITE** ? FAORRES when FATESTCD = OCCUR

Yes ☐
No ☐

Please record - **REDNESS AT INJECTION SITE (in mm)** FAORRESU

Measure the largest size across any injection site redness with the ruler provided. FAORRES when FATESTCD = LDIAM

PC Time Stamp FADTC

PC Open Date & Time [NOT SUBMITTED]

PC Close Date & Time [NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Swelling
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = ADMINISTRATION SITE
FALNKGRP = 1050/2050/3050/4050

TIMEPOINT FATPT

Is there any **SWELLING / HARDNESS AT INJECTION SITE** ? FAOBJ

FAORRES when FATESTCD = OCCUR

Yes ☐
No ☐

Please record - **SWELLING / HARDNESS AT INJECTION SITE (in mm)** FAORRESU

Measure the largest size across any injection site swelling/hardness with the ruler provided. FAORRES when FATESTCD = LDIAM

PC Time stamp FADTC

PC Open Date & Time [NOT SUBMITTED]

PC Close Date & Time [NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Headache
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = SYSTEMIC
FALNKGRP = 1070/2070/3070/4070

TIMEPOINT	FATPT
Select one response below to indicate the intensity of your **HEADACHE** FAOBJ FAORRES when FATESTCD = SEV	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	FADTC
PC Open Date & Time	[NOT SUBMITTED]
PC Close Date & Time	[NOT SUBMITTED]
Hidden Check (Programming Only)	[NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Fatigue
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = SYSTEMIC
FALNKGRP = 1080/2080/3080/4080

TIMEPOINT FATPT	
Select one response below to indicate the intensity of your **FATIGUE** FAOBJ FAORRES when FATESTCD = SEV	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	FADTC
PC Open Date & Time	[NOT SUBMITTED]
PC Close Date & Time	[NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: MuscleAche
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = SYSTEMIC
FALNKGRP = 1090/2090/3090/4090

TIMEPOINT FATPT

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY** FAOBJ = Myalgia

FAORRES when FATESTCD = SEV

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily activity ☐

PC Time stamp FADTC
PC Open Date & Time [NOT SUBMITTED]
PC Close Date & Time [NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: JointsAche
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1100/2100/3100/4100

TIMEPOINT	**FATPT**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS** **FAOBJ = Arthralgia**

FAORRES when FATESTCD = SEV

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily activity ☐

PC Time stamp	**FADTC**
PC Open Date & Time	**[NOT SUBMITTED]**
PC Close Date & Time	**[NOT SUBMITTED]**

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Nausea
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = SYSTEMIC
FALNKGRP = 1110/2110/3110/4110

TIMEPOINT FATPT

Select one response below to indicate the level of your **NAUSEA/VOMITING** FAOBJ

FAORRES when FATESTCD = SEV

- 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	FADTC
PC Open Date & Time	[NOT SUBMITTED]
PC Close Date & Time	[NOT SUBMITTED]

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Chills
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = SYSTEMIC
FALNKGRP = 1120/2120/3120/4120

TIMEPOINT	FATPT

Select one response below to indicate the intensity of **CHILLS** you are experiencing FAOBJ

FAORRES when FATESTCD = SEV

- ☐ None
- ☐ No interference with activity
- ☐ Some interference with activity not requiring medical attention
- ☐ Prevents daily activity and requires medical attention

PC Open Date & Time	[NOT SUBMITTED]
PC Close Date & Time	[NOT SUBMITTED]
PC Time stamp	FADTC

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Rash
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = SYSTEMIC
FALNKGRP = 1130/2130/3130/4130

TIMEPOINT	***FATPT***	
Select one response below if you have **RASH** ***FAOBJ***		No ☐
FAORRES when FATESTCD = OCCUR		Yes ☐
PC Open Date & Time	***[NOT SUBMITTED]***	
PC Close Date & Time	***[NOT SUBMITTED]***	
PC Time Stamp	***FADTC***	

FA = Findings About *HO= Healthcare Encounters*

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: MedAtten
Generated On: 24 Feb 2021 00

HODECOD = MAAE *HOPRESP = Y*

TIMEPOINT	*HOTERM = MEDICAL ATTENDED*	
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	*SUPPFA.QVAL when QNAM= MAAEFL* *HOOCCUR =Y*	No ☐ Yes ☐
PC Time stamp	*HOSTDTC* *HOENDTC*	
PC Open Date & Time	*[NOT SUBMITTED]*	
PC Close Date & Time	*[NOT SUBMITTED]*	
Hidden Check (Programming Only)	*[NOT SUBMITTED]*	

Notes: eDiary forms beyond 7 days will be mapped to FAAE

FA = Findings About

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: UnderarmGland
Generated On: 24 Feb 2021 00:47:22

FACAT = REACTOGENICITY
FASCAT = ADMINISTRATION SITE
FALNKGRP = 1060/2060/3060/4060

TIMEPOINT	FATPT

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** FAOBJ
Please select one response below

FAORRES when FATESTCD = SEV

- 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	FADTC
PC Open Date and Time	[NOT SUBMITTED]
PC Close Date and Time	[NOT SUBMITTED]
Hidden Check (Programming Only)	[NOT SUBMITTED]

FA = Findings About

FACAT = SAFETY

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Safety Follow Up Diary
Generated On: 24 Feb 2021 00:47:22

FASCAT = SAFETY DIARY

TIMEPOINT FATPT	
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? FAORRES when FATESTCD=CHGHLTH	No ☐ Yes ☐
FAOBJ = FOLLOW UP 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? FAORRES when FATESTCD=COVIDEXP	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. SUPPFA.QVAL when QNAM= CLIN2	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? FAORRES when FATESTCD=NEWSYMP	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 FAORRES when FATESTCD = OCCUR	
FAOBJ 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. SUPPFA.QVAL when QNAM= CLIN2J	I confirm I have read this message and will call the study clinic immediately ☐
FAOBJ = FOLLOW UP Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? FAORRES when FATESTCD= HLTHPCT	No ☐ Yes ☐

FA = Findings About

FACAT = SAFETY

v5.005 SFA: Unique eCRFs
Folder: Uniques
Form: Safety Follow Up Diary

FASCAT = SAFETY DIARY

Generated On: 24 Feb 2021 00:47:22

Please conta**SUPPFA.QVAL when QNAM= CLIN4A**firm 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 **FADTC**	
Patient Cloud Open Date & Time	**[NOT SUBMITTED]**
Patient Cloud Close Date & Time	**[NOT SUBMITTED]**