v2.039 EAB - Unique eCRFs

Generated By: (b) (6) Implementation Consultant

Generated On: 27 Jul 2020 15:10:41

All time stamps listed in this document are displayed in GMT

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

Participant ID

mRNA-1273-P201 Completion Guidelines

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

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

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?		Yes ◯
	SSORRES when SSTESTCD = COVID	No ◯

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

Only record new symptoms since the last visit

Folder OID	*[NOT SUBMITTED]*	_____

SV = Subject Visits

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

Check all that apply

Physical Exam	*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**

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

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**
ETHNIC
- Hispanic or Latino ◯
- Not Hispanic or Latino ◯
- Not Reported ◯
- Unknown ◯

Race (Check All That Apply)   **RACE** **RACE**

White		
Black	**If more than one RACE then RACE=MULTIPLE**	**If more than one RACE then RACE=MULTIPLE**
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**

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

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**   Original ○

SUPPXM.QVAL when QNAM = PROTVER   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   **DSTERM**   Withdrew Consent ○

DSCAT = DISPOSITION EVENT   Inclusion/Exclusion ○

Cohort Full ○

Other ○

If reason for screen fail is Other, specify   **DSTERM**

Was this participant screened previously?   **SUPPDM.QVAL when QNAM = PREVSCR**   Yes ○

SUPPXM.QVAL when QNAM = PREVSCR   No ○

If Yes, previous participant number   **SUPPDM.QVAL when QNAM = PREVNUM**

Enrollment Trigger   **[NOT SUBMITTED]**   **SUPPXM.QVAL when QNAM = PREVNUM**

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Inclusion/Exclusion Criteria Summary
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Did the participant meet all eligibility criteria?   Yes ◯
                                                                      No ◯

IE = Inclusion/Exclusion Criteria Not Met

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Inclusion/Exclusion Criteria
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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 ◯

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

Were any significant conditions reported??	Yes ⬭
	No ⬭

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

Condition	**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]**

FDA-CBER-2022-1614-3819946

Were vital signs assessed?   Yes ◯

VSSTAT = NOT DONE   No ◯

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

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

VSDTC

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

Height *(xxx.x)*   **VSTEST = Height**   **cm** ◯

VSORRES / VSORRESU when VSTESTCD = HEIGHT   in ◯

Weight *(xxx.x)*   **VSTEST = Weight**   **kg** ◯

VSORRES / VSORRESU when VSTESTCD = WEIGHT   lb ◯

BMI *(xxx.x)*   Fixed Unit: kg/m^2

VSTEST = Body Mass Index

VSORRES / VSORRESU when VSTESTCD = BMI

BMI units

Temperature *(xxx.x)*   **VSTEST = Temperature**   C ◯

VSORRES / VSORRESU when VSTESTCD = TEMP   F ◯

 Route of measurement   Oral ◯

VSLOC   Axillary ◯

Other ◯

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

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

VSORRES / VSORRESU when VSTESTCD = PULSE

Pulse units

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

VSORRES / VSORRESU when VSTESTCD = RESP

Respiratory Rate units

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

VSORRES / VSORRESU when VSTESTCD = SYSBP

Systolic Blood Pressure units

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

VSORRES / VSORRESU when VSTESTCD = DIABP

Diastolic Blood Pressure units

VS = Vital Signs

Height   *VSTEST = Height*   **cm** ◯   in ◯

VSORRES / VSORRESU when VSTESTCD = HEIGHT

Weight   *VSTEST = Weight*   **kg** ◯   lb ◯

VSORRES / VSORRESU when VSTESTCD = WEIGHT

Timepoint   *VSTPT*   Pre-Dose ⬤   Post-Dose ◯

Were vital signs assessed?   Yes ◯

VSSTAT = NOT DONE   No ◯

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

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

VSDTC

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

Temperature *(xxx.x)*   *VSTEST = Temperature*   C ◯   F ◯

VSORRES / VSORRESU when VSTESTCD = TEMP

Route of measurement   *VSLOC*   Oral ◯   Axillary ◯   Other ◯

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

Pulse *(xxx)*   Fixed Unit: beats/min

VSTEST = Pulse Rate

Pulse units   *VSORRES / VSORRESU when VSTESTCD = PULSE*

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

VSTEST = Respiratory Rate

Respiratory Rate units   *VSORRES / VSORRESU when VSTESTCD = RESP*

Systolic Blood Pressure *(xxx)*   Fixed Unit: mmHg

VSTEST = Systolic Blood Pressure

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

Diastolic Blood Pressure *(xxx)*   Fixed Unit: mmHg

VSTEST = Diastolic Blood Pressure

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

Timepoint   *VSTPT*   Pre-Dose ◯   Post-Dose ⬤

VS = Vital Signs

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Vital Signs - Dosing
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Were vital signs assessed?   Yes ◯

VSSTAT = NOT DONE   No ◯

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

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

VSDTC

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

Temperature *(xxx.x)*   **VSTEST = Temperature**   C ◯

VSORRES / VSORRESU when VSTESTCD = TEMP   F ◯

Route of measurement   Oral ◯

VSLOC   Axillary ◯

Other ◯

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

Pulse *(xxx)*   Fixed Unit: beats/min

VSTEST = Pulse Rate

VSORRES / VSORRESU when VSTESTCD = PULSE

Pulse units

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

VSTEST = Respiratory Rate

VSORRES / VSORRESU when VSTESTCD = RESP

Respiratory Rate units

Systolic Blood Pressure *(xxx)*   Fixed Unit: mmHg

VSTEST = Systolic Blood Pressure

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

Diastolic Blood Pressure *(xxx)*   Fixed Unit: mmHg

VSTEST = Diastolic Blood Pressure

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

FA = Findings About

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

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

Collection date *(dd MMM yyyy)*   **LBDTC**

Lab panel	**LBCAT**	Hematology ●
		Chemistry ○
		Serology ○
		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]**

Lab panel	**LBCAT**	Hematology ○
		Chemistry ●
		Serology ○
		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]**

Lab panel	**LBCAT**	Hematology ○
		Chemistry ○
		Serology ○
		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

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

Collection date *(dd MMM yyyy)* `LBDTC`

Lab panel `LBCAT`
- Hematology ⬤
- Chemistry ◯
- Serology ◯
- Coagulation ◯

Was the sample collected?
- Yes ◯
- `LBSTAT = NOT DONE` 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?
- Yes ◯
- `LBSTAT = NOT DONE` 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?
- Yes ◯
- `LBSTAT = NOT DONE` 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 ◯

LB = Laboratory Test Results

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

	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

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

Collection date *(dd MMM yyyy)* `LBDTC`

Lab panel `LBCAT`

- Hematology ⬤
- Chemistry ◯
- Serology ◯
- Coagulation ◯
- FSH ◯

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]`

Lab panel `LBCAT`

- Hematology ◯
- Chemistry ⬤
- Serology ◯
- Coagulation ◯
- FSH ◯

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]`

Lab panel `LBCAT`

- Hematology ◯
- Chemistry ◯
- Serology ⬤
- Coagulation ◯
- FSH ◯

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

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

Lab panel

LBCAT

Hematology ◯
Chemistry ◯
Serology ◯
Coagulation ⬤
FSH ◯

Was the sample collected?

LBSTAT = NOT DONE

Yes ◯
No ◯

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 ◯
FSH ⬤

Was the sample collected?

LBSTAT = NOT DONE

Yes ◯
No ◯

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

LBDTC

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

MB = Microbiology Specimen

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

MBCAT = SARS-CoV-2 for Part A
MBCAT = BIOFIRE for Part B

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 ◯
MBSTAT = NOT DONE   No ◯

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 ◯
MBSTAT = NOT DONE   No ◯

Collection time *(00:00 - 23:59)*   *MBDTC*
Collection date and time (derived)   *[NOT SUBMITTED]*

v2.039 EAB: Unique eCRFs

MBCAT = SARS-CoV-2 for Part A
MBCAT = BIOFIRE for Part B

Folder: Uniques

Form: Central Laboratory - Nasopharyngeal Swab and Blood Collection for SARS-CoV-2

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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 ◯
- **MBSTAT = NOT DONE** No ◯

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 ◯
- **MBSTAT = NOT DONE** No ◯

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 ◯
- **MBSTAT = NOT DONE** No ◯

Collection time *(00:00 - 23:59)*	**MBDTC**
Collection date and time (derived)	**[NOT SUBMITTED]**

LB = Laboratory Test Results

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Unscheduled
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Collection date *(dd MMM yyyy)* `LBDTC`

Lab panel

Hematology ◯
`LBCAT` 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

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

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

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Pregnancy Test
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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**

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

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 ◯

v2.039 EAB: Unique eCRFs

DSCAT = DISPOSITION EVENT

Folder: Uniques

DSSCAT = STUDY TREATMENT

Form: Exposure

Generated On: 27 Jul 2020 15:10:41   **ECPRESP = Y**

Was study treatment given?   **ECOCCUR = Y** Yes ◯

DSTERM / DSDECOD = COMPLETED when Visit= Visit 4 Day 29 and Treatment given=Yes   **ECOCCUR = N** No ◯

If No, reason not given   **ECREASOC**

Participant declined due to Adverse Event ◯

Physician withheld dose due to Adverse Event ◯

Death ◯

Lost To Follow-Up ◯

Physician Decision ◯

Pregnancy ◯

Protocol Deviation ◯

Study Terminated by Sponsor ◯

Withdrawal of Consent by Participant ◯

Other ◯

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify   **ECREASOC**

What was the study treatment?   **[NOT SUBMITTED]**

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

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

EXSTDTC   **ECSTDTC**

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**

IS = Immunogenicity Specimen Assessments

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Central Laboratory - Antibody-Mediated Immunogenicity
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Lab panel	`ISCAT`	Antibody-mediated ⬤ Immunogenicity
Was the sample collected?		Yes ◯
	`ISSTAT = NOT DONE`	No ◯
Collection date *(dd MMM yyyy)*	`ISDTC`	
Collection time *(00:00-23:59)*		Fixed Unit: (24 HR)
	`ISDTC`	
Collection date and time (derived)	`[NOT SUBMITTED]`	

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

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

v2.039 EAB: Unique eCRFs
Folder: Uniques   *ERCAT = COVID-19 EXPOSURE*
Form: SARS-CoV-2 or COVID-19 Exposure Assessment
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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

Health Care Facility   *ERTERM*   *EROCCUR*

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

v2.039 EAB: 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**

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

`CECAT = REACTOGENICITY`

`CETERM`   `CEPRESP = Y`   `FAOBJ`   `FACAT = REACTOGENICITY`

`CELNKGRP = 1010/2010`   `FALNKGRP = 1010/2010`

| 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 ◯ |
| | `CESTAT = NOT DONE`   `FASTAT= NOT DONE` | No ◯ |

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`	Grade 0 = No rash ◯
	`CEOCCUR = Y`	Grade 1 = Localized rash, without associated symptoms ◯
`FAORRES when FATESTCD = SEV`		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` |

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

CECAT = REACTOGENICITY

CETERM *CEPRESP = Y* *FAOBJ* *FACAT = REACTOGENICITY*

CELNKGRP = 1020/2020 *FALNKGRP = 1020/2020*

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 ◯
CESTAT = NOT DONE *FASTAT= NOT DONE*		No ◯

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?	*CEOCCUR = Y*	Yes ◯
FAORRES when FATESTCD = OCCUR	*CEOCCUR = N*	No ◯

Additional relevant information   *COVAL* *COREF = LYMPHCOM*

v2.039 EAB (778)

MB = Microbiology Specimen

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

Date of Test   `MBDTC`

Institution Name   `MBNAM`

Diagnostic Test Performed   Nasopharyngeal Swab ◯

`MBSPEC`   Blood Test ◯

                                                                                Other ◯

 Other, Specify   `SUPPMB.QVAL when QNAM=LDTSTOTH`

Type of Diagnostic Test (if known):   `SUPPMB.QVAL when QNAM=LDTTYPE`

COVID-19 Result   Positive ◯

`MBORRES`   Negative ◯

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

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

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

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

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

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

	Intraperiteoneal ○
CMROUTE	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?	Yes ○
SUPPCM.QVAL when QNAM = CMSOL	No ○

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

Were any concomitant procedures performed?	Yes ◯
	No ◯

If yes, please complete Concomitant Procedures form.

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PR = Procedures

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

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**

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

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

If Yes, enter details on the Adverse Events form.

AE = Adverse Events   **HO= Healthcare Encounters**   **FA = Findings About**

v2.039 EAB: Unique eCRFs   **CE = Clinical Events**   **Notes:** --SPID will be used to link records
Folder: Uniques
Form: Adverse Events   **FACAT = REACTOGENICITY**
Generated On: 27 Jul 2020 15:10:41

Field	Mapping		
Adverse event	AETERM	CETERM	FAOBJ
Was this a medically-attended AE?	AESCAT = PIMMC when Yes		Yes ◯
SUPPFA.QVAL when QNAM = MAAEFL	SUPPAE.QVAL when QNAM = AEMAFL		No ◯
Was this a Solicited Adverse Reaction?	AECAT = REACTOGENICITY when Yes		Yes ◯
	SUPPAE.QVAL when QNAM = AESOFL		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	FADTC	Fixed Unit: (24 HR)
AE End Date and Time (derived)	[NOT SUBMITTED]		

Severity

FAORRES when FATESTCD = SEV   **SUPPCE.QVAL when QNAM = AESEVX**

		Severity
	AETOXGR	Grade 1/Mild ◯
		Grade 2/Moderate ◯
		Grade 3/Severe ◯
	AESEV	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		Yes ◯
HODECOD = ICU	HOOCCUR	No ◯ Unknown ◯
Number of Days in ICU	HODUR	
Persistent or significant disability or incapacity	AESDISAB	
Congenital anomaly or birth defect	AESCONG	

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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

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

DSCAT = DISPOSITION EVENT

DSSCAT = STUDY TREATMENT

DSSTDTC

Date of dosing discontinuation (dd MMM yyyy)

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	◯

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**

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: End of Study / Study Discontinuation   *DSCAT = DISPOSITION EVENT*
Generated On: 27 Jul 2020 15:10:41   *DSSCAT = END OF STUDY*

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

Reason for discontinuation

	Adverse Event (Other) ◯
	Adverse Event (COVID-19 infection) ◯
DSTERM *DSTERM = COMPLETED*	Complete ◯
DSDECOD	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

	Adverse event ◯
DSTERM when death	Unknown ◯
DDORRES where DDTESTCD= PRCDTH	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?

	Yes ◯
DDORRES where DDTESTCD= AUTOPIND	No ◯
	Unknown ◯

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

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

Continuing Flag

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

Visit

VISIT

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

Case Report Form

Visit Date	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	**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	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Central Laboratory - Antibody-Mediated Immunogenicity	
Safety Call	
Solicited Rash	
Lymphadenopathy	

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VE= VISIT EVENTS

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

Dosing Discontinuation	
End of Study / Study Discontinuation	*SUPPVE.QVAL when QNAM = MISSASS*
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	

Form: Temp
Generated On: 2

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 ◯
VSSTAT = NOT DONE Missing records will also be considered as NOT DONE	No ◯
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 ◯
SUPPVS.QVAL when QNAM = MEDTAK	No ◯

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] _____

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

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

CECAT = REACTOGENICITY   *FACAT = REACTOGENICITY*

CESCAT = ADMINISTRATION SITE   *FASCAT = ADMINISTRATION SITE*

TIMEPOINT   *CEPRESP = Y*   *SUPPFA.QVAL when QNAM= CRFTMPT*

Please record - **PAIN AT INJECTION SITE.**   *FAOBJ = Pain*   *CEOCCUR = N*   None ◯
Please select one response below   Does not interfere with activity ◯

FAORRES when FATESTCD = SEV   *CETERM=Pain*   Repeated use of over-the-counter ◯
pain reliever > 24 hours or

CELNKGRP = 1030/2030   interferes with activity

FALNKGRP = 1030/2030   *CEOCCUR = Y*   Any use of prescription pain ◯
reliever or prevents daily activity

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

Please record - **REDNESS AT INJECTION SITE (in mm)**   *FAORRESU*   *FAOBJ*   *CELNKGRP = 1040/2040*

Measure the largest size across any injection site redness with the   *FALNKGRP = 1040/2040*
ruler provided.   *FAORRES when FATESTCD = LDIAM*

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**   *FAOBJ*   *CELNKGRP = 1050/2050*
(in mm)   *FAORRESU*

Measure the largest size across any injection site swelling/hardness   *FALNKGRP = 1050/2050*
with the ruler provided.   *FAORRES when FATESTCD = LDIAM*

Please record - **UNDERARM GLAND SWELLING OR**   *CEOCCUR = N*   None ◯
TENDERNESS.   *FAOBJ*   *CETERM*   Does not interfere with activity ◯
Please select one response below   Repeated use of over-the-counter ◯
pain reliever > 24 hours or

FAORRES when FATESTCD = SEV   interferes with some activity

CELNKGRP = 1060/2060   *CEOCCUR = Y*   Any use of prescription pain ◯
reliever or prevents daily activity

FALNKGRP = 1060/2060   *FADTC*

PC Open Date & Time   [NOT SUBMITTED]

PC Close Date & Time   [NOT SUBMITTED]

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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**

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

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

TIMEPOINT   CEPRESP = Y   SUPPFA.QVAL when QNAM= CRFTMPT

HEADACHE   CELNKGRP = 1070/2070   FALNKGRP = 1070/2070   CEOCCUR = N   None ◯

No interference with activity ◯

FAOBJ   CETERM

FAORRES when FATESTCD = SEV   Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ◯

CEOCCUR = Y   Any use of prescription pain reliever or prevents daily activity ◯

FATIGUE   CELNKGRP = 1080/2080   FALNKGRP = 1080/2080   CEOCCUR = N   None ◯

No interference with activity ◯

FAOBJ   CETERM   Some interference with activity ◯

FAORRES when FATESTCD = SEV   CEOCCUR = Y   Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY   CETERM = Myalgia   CEOCCUR = N   None ◯

CELNKGRP = 1090/2090   FALNKGRP = 1090/2090   No interference with activity ◯

FAOBJ = Myalgia   Some interference with activity ◯

FAORRES when FATESTCD = SEV   Significant; prevents daily activity ◯

CEOCCUR = Y

JOINT ACHES IN SEVERAL JOINTS   CEOCCUR = N   None ◯

CELNKGRP= 1100/2100   FALNKGRP = 1100/2100   No interference with activity ◯

FAOBJ = Arthralgia   CETERM = Arthralgia   Some interference with activity ◯

FAORRES when FATESTCD = SEV   CEOCCUR = Y   Significant; prevents daily activity ◯

NAUSEA/VOMITING   FAOBJ   CETERM   CEOCCUR = N   None ◯

CELNKGRP = 1110/2110   FALNKGRP = 1110/2110   No interference with activity or 1-2 episodes/24 hours ◯

FAORRES when FATESTCD = SEV   Some interference with activity or >2 episodes/24 hours ◯

CEOCCUR = Y   Prevents daily activity, requires outpatient IV hydration ◯

CHILLS   FAOBJ   CETERM   CEOCCUR = N   None ◯

CELNKGRP = 1120/2120   FALNKGRP = 1120/2120   No interference with activity ◯

FAORRES when FATESTCD = SEV   Some interference with activity not requiring medical attention ◯

CEOCCUR = Y   Prevents daily activity and requires medical attention ◯

RASH   FAOBJ   CETERM   CEOCCUR = N   No ◯

CELNKGRP = 1130/2130   FALNKGRP = 1130/2130   FAORRES when FATESTCD = OCCUR

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

v2.039 EAB: Unique eCRFs

Folder: Uniques

Form: General

Generated On: 27 Jul 2020 15:10:41   `HODECOD = MAAE`   `HOPRESP = Y`

`HOTERM = MEDICAL ATTENDED`   Yes ◯

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

`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]

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = ADMINISTRATION SITE

FALNKGRP = 1030/2030

TIMEPOINT	*SUPPFA.QVAL when QNAM= CRFTMPT*

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]	

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = ADMINISTRATION SITE

FALNKGRP = 1040/2040

TIMEPOINT   FAOBJ = Erythema   SUPPFA.QVAL when QNAM= CRFTMPT

Is there any **REDNESS AT INJECTION SITE** ?   Yes ◯

FAORRES when FATESTCD = OCCUR   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]

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = ADMINISTRATION SITE

FALNKGRP = 1050/2050

TIMEPOINT	SUPPFA.QVAL when QNAM= CRFTMPT

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

FAORRES when FATESTCD = OCCUR   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]

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1070/2070

TIMEPOINT	SUPPFA.QVAL when QNAM= CRFTMPT

Select one response below to indicate the intensity of your
HEADACHE FAOBJ

None ◯

No interference with activity ◯

FAORRES when FATESTCD = SEV

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 ◯

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

FA = Findings About

v2.039 EAB: Unique eCRFs

Folder: Uniques

Form: Fatigue

Generated On: 27 Jul 2020 15:10:41

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1080/2080

TIMEPOINT

SUPPFA.QVAL when QNAM= CRFTMPT

Select one response below to indicate the intensity of your

FATIGUE *FAOBJ*

None ◯

No interference with activity ◯

Some interference with activity ◯

FAORRES when FATESTCD = SEV

Significant; prevents daily activity ◯

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

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1090/2090

TIMEPOINT

SUPPFA.QVAL when QNAM= CRFTMPT

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

None ◯
No interference with activity ◯
Some interference with activity ◯
Significant; prevents daily activity ◯

FAORRES when FATESTCD = SEV

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

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1100/2100

TIMEPOINT

SUPPFA.QVAL when QNAM= CRFTMPT

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

None	◯
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

FAORRES when FATESTCD = SEV

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

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1110/2110

TIMEPOINT

SUPPFA.QVAL when QNAM= CRFTMPT

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]*

FDA-CBER-2022-1614-3819994

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1120/2120

SUPPFA.QVAL when QNAM= CRFTMPT

TIMEPOINT

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

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

FALNKGRP = 1130/2130

TIMEPOINT

SUPPFA.QVAL when QNAM= CRFTMPT

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**

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: MedAtten
Generated On: 27 Jul 2020 15　　HODECOD = MAAE　　HOPRESP = Y

　　HOTERM = MEDICAL ATTENDED

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

FA = Findings About

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

FACAT = REACTOGENICITY

FASCAT = ADMINISTRATION SITE

FALNKGRP = 1060/2060

TIMEPOINT

SUPPFA.QVAL when QNAM= CRFTMPT

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]	

FDA-CBER-2022-1614-3819998

FA = Findings About

FACAT = SAFETY

v2.039 EAB: Unique eCRFs
Folder: Uniques
Form: Safety Follow Up Diary

FASCAT = SAFETY DIARY

Generated On: 27 Jul 2020 15:10:41

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**	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

FAOBJ

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 ◯

v2.039 EAB (778)

FDA-CBER-2022-1614-3819999

FA = Findings About

FACAT = SAFETY

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

FASCAT = SAFETY DIARY

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]*	