

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

Generated By: (b) (6) Implementation Consultant

Generated On: 30 Apr 2021 19:52:48

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**[NOT SUBMITTED]**

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

**Folder: Uniques**

**Form: Participant Creation**

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Participant ID

[mRNA-1273-P301 Completion Guidelines](#)

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**Form: Visit Date**

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|   |                                 |
|---|---------------------------------|
| Was this visit performed?                                       | Yes <input type="checkbox"/>    |
|   | No <input type="checkbox"/>     |
| Visit date (dd MMM yyyy)  | <div>[NOT SUBMITTED]</div>      |
| Was visit performed at the participant's home or at the clinic? |                                 |
|   | <div>SVCNTMOD</div>             |
|   | Home <input type="checkbox"/>   |
|   | Clinic <input type="checkbox"/> |

**DM = Demographics****DS = Disposition****MH = Medical History****v13.005 Publish Checks to Prod CRF Version 1725: Uniques****Folder: Uniques****DSCAT = PROTOCOL MILESTONE****Form: Randomization****DSTERM = RANDOMIZED****Generated On: 30 Apr 2021 19:52:48**

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?

>=18 and <65 years and not at risk ☐**SUPPDM.QVAL when QNAM = COHORT**>=18 and <65 years and at risk ☐**MHCAT = RISK FACTOR FOR COVID-19**>=65 years ☐

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Yes ☐No ☐**MHTERM = LUNG DISEASE**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Yes ☐No ☐**MHTERM = CARDIAC DISEASE****MHOCCUR**

Severe obesity (body mass index &gt; or = 40kg/m2)

Yes ☐No ☐**MHTERM = SEVERE OBESITY**

Diabetes (Type I, Type 2, or gestational)

Yes ☐No ☐**MHTERM = DIABETES**

Liver Disease

Yes ☐No ☐**MHTERM = LIVER DISEASE**

Human Immunodeficiency Virus (HIV) infection

Yes ☐No ☐**MHTERM = HIV**

**DS = Disposition****DM = Demographics**

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**DSCAT = PROTOCOL MILESTONE**

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**DSSCAT = OPEN LABEL**

Form: Unblinding

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Date of updated informed consent (dd MMM yyyy)

**DSSTDTC when DSTERM=INFORMED CONSENT OBTAINED**

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

**SUPPDM.QVAL when QNAM = UNBLNA**

Was the participant unblinded?

Yes ☐**SUPPDM.QVAL when QNAM = UNBLNDYN**No ☐

Under what version of the Protocol was the Participant unblinded?

Amendment 5 ☐**SUPPDM.QVAL when QNAM = UNBLPROT**Amendment 6 or later ☐

Date of unblinding (dd MMM yyyy)

**DSSTDTC when DSTERM=TREATMENT UNBLINDED**

Participant randomization assignment

mRNA-1273 ☐**[NOT SUBMITTED]**Placebo ☐

Actual Dose 1

mRNA-1273 ☐**[NOT SUBMITTED]**Placebo ☐Not Administered ☐

Actual Dose 2

mRNA-1273 ☐**[NOT SUBMITTED]**Placebo ☐Not Administered ☐

Will participant receive mRNA-1273?

Yes ☐**SUPPDM.QVAL when QNAM = UNBLMRNA**No ☐

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Form: Unscheduled Visit Assessment

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|   |                |
|---|----------------|
| Visit Date  | <b>SVSTDTC</b> |
| <b>Please check all assessments that apply for this visit</b> |                |
| Physical Exam   | <b>SVUPDES</b> |
| Vital Signs   | <b>SVUPDES</b> |
| Immunogenicity Assessment                                     | <b>SVUPDES</b> |
| Pregnancy Test  | <b>SVUPDES</b> |

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Form: Demographics

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|   |                                       |         |   |
|---|---------------------------------------|---------|---|
| Date of Birth (MMM yyyy)                  | BRTHDTC                               | BRTHDTC |   |
| Age                                       |                                       | AGE     | AGE   |
| Sex                                       | SEX                                   | SEX     | Female <input type="checkbox"/>                 |
|   |                                       |         | Male <input type="checkbox"/>                   |
| Ethnicity                                 |                                       |         | Hispanic or Latino <input type="checkbox"/>     |
|   | ETHNIC                                | ETHNIC  | Not Hispanic or Latino <input type="checkbox"/> |
|   |                                       |         | Not Reported <input type="checkbox"/>           |
|   |                                       |         | Unknown <input type="checkbox"/>                |
| Race (Check All That Apply)               | RACE                                  |         | RACE  |
| White                                     | RACE = MULTIPLE                       |         | RACE = MULTIPLE                                 |
| Black                                     |                                       |         |   |
| Asian                                     |                                       |         |   |
| American Indian or Alaska Native          | SUPPDM.QVAL when QNAM = RACE1 - RACE6 |         |   |
| Native Hawaiian or other Pacific Islander |                                       |         |   |
| Other                                     |                                       |         |   |
| If race is Other, specify                 | SUPPDM.QVAL when QNAM = RACEOTH       |         |   |
| Unknown                                   |                                       |         |   |
| Not reported                              |                                       |         |   |

**DM = Demographics****DS = Disposition****XM = Multiple participation****IE = Inclusion/Exclusion Criteria Not Met**

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Folder: Uniques **DSCAT = PROTOCOL MILESTONE**

Form: Enrollment

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Date of Informed Consent (dd MMM yyyy)

**DSSTDTC when DSTERM  
= INFORMED CONSENT  
OBTAINED****RFICDTC****RFICDTC**

Protocol Version

Amendment 1 ☐Amendment 2 ☐Amendment 3 ☐Amendment 4 ☐Amendment 5 ☐**SUPPIE.QVAL when QNAM = PROTVER**

Was participant enrolled in the study?

Yes ☐**SUPPDS.QVAL when QNAM = ENROLYN**No ☐

If No, indicate reason for screen fail

Withdrew Consent ☐**DSCAT = DISPOSITION EVENT****DSTERM**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 ☐No ☐

If Yes, previous participant number

**SUBJID****SUPPDM.QVAL when QNAM = SUBJID1**



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**Folder: Uniques**

**Form: Inclusion/Exclusion Criteria Summary**

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|  |                              |
|--|------------------------------|
| Did the participant meet all eligibility criteria? | Yes <input type="checkbox"/> |
|  | No <input type="checkbox"/>  |

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Form: Inclusion/Exclusion Criteria

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|   |   |                                    |
|---|---|------------------------------------|
| Select inclusion criteria not met and/or exclusion criteria met |   |                                    |
| Criterion Type  | <b>IECAT = INCLUSION</b>                  | Inclusion <input type="checkbox"/> |
|   | <b>IECAT = EXCLUSION</b>                  | Exclusion <input type="checkbox"/> |
| Criterion Identifier  | <b>IETESTCD</b>                           | 1 <input type="checkbox"/>         |
|   |   | 2 <input type="checkbox"/>         |
|   | <b>IEORRES = N when IECAT = INCLUSION</b> | 3 <input type="checkbox"/>         |
|   | <b>IEORRES = Y when IECAT = EXCLUSION</b> | 4 <input type="checkbox"/>         |
|   |   | 5 <input type="checkbox"/>         |
|   |   | 6 <input type="checkbox"/>         |
|   |   | 7 <input type="checkbox"/>         |
|   |   | 8 <input type="checkbox"/>         |
|   |   | 9 <input type="checkbox"/>         |
|   |   | 10 <input type="checkbox"/>        |
|   |   | 11 <input type="checkbox"/>        |
|   |   | 12 <input type="checkbox"/>        |
|   |   | 13 <input type="checkbox"/>        |
|   |   | 14 <input type="checkbox"/>        |
|   |   | 15 <input type="checkbox"/>        |
|   |   | 16 <input type="checkbox"/>        |
|   |   | 17 <input type="checkbox"/>        |
|   |   | 18 <input type="checkbox"/>        |
|   |   | 19 <input type="checkbox"/>        |
|   |   | 20 <input type="checkbox"/>        |
|   |   | 21 <input type="checkbox"/>        |
|   |   | 22 <input type="checkbox"/>        |
|   |   | 23 <input type="checkbox"/>        |
|   |   | 24 <input type="checkbox"/>        |
|   |   | 25 <input type="checkbox"/>        |
|   |   | 26 <input type="checkbox"/>        |
|   |   | 27 <input type="checkbox"/>        |
|   |   | 28 <input type="checkbox"/>        |
|   |   | 29 <input type="checkbox"/>        |
|   |   | 30 <input type="checkbox"/>        |

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Form: Medical History Summary

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|   |                              |
|---|------------------------------|
| Were any significant conditions reported? | Yes <input type="checkbox"/> |
|   | No <input type="checkbox"/>  |

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

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**Form: Medical History**

**MHCAT = GENERAL**

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|   |   |                              |
|---|---|------------------------------|
| Condition   | <b>MHTERM</b>                           |                              |
| Start date (dd MMM yyyy)                          | <b>SUPPMH.QVAL when QNAM = MHSTUNKC</b> | <b>MHSTDTC</b>               |
| Start date completely unknown                     |   |                              |
| Condition ongoing at study entry                  | <b>MHENRTPT = ONGOING</b>               | Yes <input type="checkbox"/> |
|   |   | No <input type="checkbox"/>  |
| If No, please specify the stop date (dd MMM yyyy) | <b>MHENDTC</b>                          |                              |
| Stop date completely unknown                      | <b>SUPPMH.QVAL when QNAM = MHENUNKC</b> |                              |

**VS = Vital Signs**

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**VSCAT = VITAL SIGNS**

Form: Vital Signs

Generated On: 30 Apr 2021 19:52:48

Were vital signs assessed?

Yes ☐**VSSTAT = NOT DONE** No ☐

Date of assessment (dd MMM yyyy)

Time of assessment (00:00-23:59)

**VSDTC**

Fixed Unit: (24 HR)

Height (xxx.x)

cm ☐**VSTEST = Height****VSORRES / VSORRESU when VSTESTCD = HEIGHT**in ☐

Weight (xxx.x)

kg ☐**VSTEST = Weight****VSORRES / VSORRESU when VSTESTCD = WEIGHT**lb ☐

BMI (xxx.x)

Fixed Unit: kg/m<sup>2</sup>**VSTEST = Body Mass Index****VSORRES / VSORRESU when VSTESTCD = BMI**

Temperature (xxx.x)

C ☐**VSTEST = Temperature****VSORRES / VSORRESU when VSTESTCD = TEMP**F ☐

Route of measurement

Oral ☐Axillary ☐**VSLOC**Other ☐

If Other, specify

**SUPPVS.QVAL when QNAM = VSLOCSP**

Pulse (xxx)

Fixed Unit: beats/min

**VSTEST = Pulse Rate****VSORRES / VSORRESU when VSTESTCD = PULSE**

Respiratory Rate (xxx)

Fixed Unit: breaths/min

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

Systolic Blood Pressure (xxx)

Fixed Unit: mmHg

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

Diastolic Blood Pressure (xxx)

Fixed Unit: mmHg

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

**VS = Vital Signs**

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**VSCAT = VITAL SIGNS**

Form: Vital Signs - Dosing

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Height **VSORRES / VSORRESU when VSTESTCD = HEIGHT** cm ☐  
**VSTEST = Height** in ☐

Weight **VSORRES / VSORRESU when VSTESTCD = WEIGHT** kg ☐  
**VSTEST = Weight** lb ☐

BMI (xxx.x) **VSORRES / VSORRESU when VSTESTCD = BMI**

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) Fixed Unit: (24 HR)

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

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

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

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

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

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

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

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) Fixed Unit: (24 HR)

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## VSCAT = VITAL SIGNS

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Form: Vital Signs - Dosing

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Temperature (xxx.x)

VSTEST = Temperature

VSORRES / VSORRESU when VSTESTCD = TEMP

C ☐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

Respiratory Rate (xxx)

Fixed Unit: breaths/min

VSTEST = Respiratory Rate

VSORRES / VSORRESU when VSTESTCD = RESP

Systolic Blood Pressure (xxx)

Fixed Unit: mmHg

VSTEST = Systolic Blood Pressure

VSORRES / VSORRESU when VSTESTCD = SYSBP

Diastolic Blood Pressure (xxx)

Fixed Unit: mmHg

VSTEST = Diastolic Blood Pressure

VSORRES / VSORRESU when VSTESTCD = DIABP

FACAT = PHYSICAL EXAMINATION

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Form: Physical Examination

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Was the physical examination performed?

Yes ☐

FAOBJ

FAORRES when FATESTCD = OCCUR

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.*



**RP = Reproductive System Findings**

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Form: Childbearing Potential

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|   |                                |                             |                              |
|---|--------------------------------|-----------------------------|------------------------------|
| Date of assessment (dd MMM yyyy)                            | RPDTC                          |                             |                              |
| Is the participant of childbearing potential?               | RPTSTCD=CHILDPOT               | RPORRES                     | Yes <input type="checkbox"/> |
|   |                                |                             | No <input type="checkbox"/>  |
| If No, what is the reason?                                  | SUPPRP.QVAL when QNAM=CBRSN    | Surgically sterile          | <input type="checkbox"/>     |
|   |                                | Post-menopausal             | <input type="checkbox"/>     |
|   |                                | Partner medically sterile   | <input type="checkbox"/>     |
|   |                                | Not reached age of Menarche | <input type="checkbox"/>     |
|   |                                | Other                       | <input type="checkbox"/>     |
| 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 |                             |                              |

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Form: Pregnancy Test

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**LBCAT = PREGNANCY TEST**Was the pregnancy test performed? **LBTESTCD = HCG** Yes ☐**LBTEST=Choriogonadotropin Beta; Pregnancy Test** **LBSTAT = NOT DONE** No ☐Date of test (dd MMM yyyy) **LBDTC** \_\_\_\_\_Test performed **LBSPEC** Urine ☐Serum ☐Result **LBORRES when LBTESTCD = HCG** Positive ☐Negative ☐Was FSH sample collected? **LBCAT = CHEMISTRY** Yes ☐**LBTEST=Follicle Stimulating Hormone** **LBTESTCD = FSH** **LBSTAT = NOT DONE** No ☐

Collection date \_\_\_\_\_

Collection time **LBDTC** \_\_\_\_\_

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

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Form: Exposure

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**ECRESP = Y****DSCAT = DISPOSITION EVENT****DSSCAT = STUDY TREATMENT**

Was study treatment given?

**ECOCCUR**Yes ☐  
No ☐**DSTERM/ DSDECOD = COMPLETED, at Visit 2 Day 29, when Yes**

If No, reason not given

Participant declined due to ☐  
Adverse Event ☐  
Physician withheld dose due to ☐  
Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by ☐  
Participant ☐  
Confirmed COVID-19 ☐  
Other ☐**ECREASOC**If reason is Physician Decision, Withdrawal of Consent by  
Participant, Protocol Deviation, or Other, specify**ECREASOC****SUPPEC.QVAL when QNAM =  
EXREASSP / EXREASP1 / EXREASP2  
when text > 200. split into multiple**

What was the study treatment?

**[NOT SUBMITTED]**

What was the study treatment? (Unblinded)

**[NOT SUBMITTED]**

What was the treatment date? (dd MMM yyyy)

**EXSTDTC****ECSTDTC**

What was the treatment time? (00:00-23:59)

Fixed Unit: (24 HR)

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**

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Form: Immunogenicity Assessment

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ISCAT = IMMUNOGENICITY ASSESSMENT

Was the sample collected? Yes ☐ No ☐

ISSTAT = NOT DONE

Collection date (dd MMM yyyy)

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

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Form: Central Laboratory - Nasopharyngeal Swab

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**MBCAT = SARS-CoV-2****MBTESTCD = SARSCOV2**

|                                 |                          |   |
|---------------------------------|--------------------------|---|
| Collection date (dd MMM yyyy)   | <b>MBDTC</b>             |   |
| Lab Test                        |                          | Nasopharyngeal Swab 1 <input checked="" type="radio"/>            |
|                                 | <b>MBSCAT</b>            | Nasopharyngeal Swab 2 <input type="radio"/>                       |
|                                 |                          | Blood Collection for exposure to SARS-CoV-2 <input type="radio"/> |
| Was the sample collected?       |                          | Yes <input type="radio"/>   |
|                                 | <b>MBSTAT = NOT DONE</b> | No <input type="radio"/>  |
| Collection time (00:00 - 23:59) | <b>MBDTC</b>             |   |
| Lab Test                        |                          | Nasopharyngeal Swab 1 <input type="radio"/>                       |
|                                 | <b>MBSCAT</b>            | Nasopharyngeal Swab 2 <input checked="" type="radio"/>            |
|                                 |                          | Blood Collection for exposure to SARS-CoV-2 <input type="radio"/> |
| Was the sample collected?       |                          | Yes <input type="radio"/>   |
|                                 | <b>MBSTAT = NOT DONE</b> | No <input type="radio"/>  |
| Collection time (00:00 - 23:59) | <b>MBDTC</b>             |   |

**MB = Microbiology Specimen**

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Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 30 Apr 2021 19:52:48

**MBCAT = SARS-CoV-2**

**MBTESTCD = SARSCOV2**

Was the sample collected?

Yes ☐

No ☐

**MBSTAT = NOT DONE**

Collection date (dd MMM yyyy)

**MBDTC**

Collection time (00:00 - 23:59)

**SV = Subject Visits**

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Form: Safety Call

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**SVPRESP = Y**

Was Contact Attempted?

**SVOCUR**Yes ☐No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

**SVSTDTC**

Please select one status for the follow-up contact

**SVCNTMOD = TELEPHONE****SVTERM**Contact Made ☐Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments***SVREASOC**

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**Form: Adverse Events Summary**

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|  |                              |
|--|------------------------------|
| Did the participant experience any adverse events? | Yes <input type="checkbox"/> |
|  | No <input type="checkbox"/>  |

**If Yes, enter details on the Adverse Events form.**



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

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

Note: --SPIDx will be used to link records

Links to Prod CRF Version 1725: Uniques

**CECAT = ADVERSE EVENT when the AE is COVID-19**

**CECAT = REACTOGENICITY when AESOFL=Y**

Form: Adverse Events

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**FACAT = REACTOGENICITY**

AEID **AESPID** **HOSPID**

Adverse event **AETERM** **FAOBJ** **CETERM**

Was this a medically-attended AE?

**AESCAT = PIMMC when Yes**

Yes ☐

**CEOCCUR=Y**

**SUPPCE.QVAL when QNAM = MAAEFL**

**SUPPAE.QVAL when QNAM = MAAEFL**

No ☐

**SUPPFA.QVAL when QNAM = MAAEFL**

Was this a Solicited Adverse Reaction?

**AECAT = REACTOGENICITY when Yes**

Yes ☐

**SUPPAE.QVAL when QNAM = AESOFL**

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

**SUPPAE.QVAL when QNAM = AECVDIAG**

No ☐

Start date (dd MMM yyyy)

**AESTDTC**

**CESTDTC**

**FADTC**

Start time (00:00-23:59)

Fixed Unit: (24 HR)

Ongoing?

Yes ☐

**AEENRF**

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

**AEENDTC**

**FADTC**

**CEENDTC**

Fixed Unit: (24 HR)

Severity

**FAORRES when FATESTCD = SEV**

**CETOXGR**

**AETOXGR**

**AESEV**

**CESEV**

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

**AESER**

No ☐

AE is serious due To (check all that apply)

Death

**AESDTH**

Life threatening

**AESLIFE**

Requires inpatient or prolongation of existing Hospitalization

**AESHOSP**

Hospital Admission Date (dd MMM yyyy)

**HODECOD = HOSPITAL**

**HOSTDTC**

Hospital Discharge Date (dd MMM yyyy)

**SUPPAE.QVAL when QNAM = AEHOSPST/ AEHOSPEN**

**HOENDTC**

Admitted to ICU?

**HOTERM**

Yes ☐

**HODECOD = ICU**

**HOCAT = ADVERSE EVENTS**

**HOCCUR**

No ☐

Unknown ☐

Number of Days in ICU

**HODUR**

Persistent or significant disability or incapacity

**AESDISAB**

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Form: Adverse Events

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|  |  |  |
|--|--|--|
| Congenital anomaly or birth defect   | <b>AESCONG</b>                         |  |
| Other medically important event  | <b>AESMIE</b>                          |  |
| Relationship to investigational product                                      | <b>AEREL</b>                           | Not Related <input type="checkbox"/><br>Related <input type="checkbox"/><br>Not Applicable <input type="checkbox"/>  |
| Relationship to Study Procedure  | <b>AERELNST</b>                        | Not Related <input type="checkbox"/><br>Related <input type="checkbox"/><br>Not Applicable <input type="checkbox"/>  |
| Action taken with investigational product                                    | <b>AEACN</b>                           | None <input type="checkbox"/><br>Dose Delayed <input type="checkbox"/><br>Investigational Product <input type="checkbox"/><br>Withdrawn <input type="checkbox"/><br>Not Applicable <input type="checkbox"/>  |
| Other action taken (check all that apply)                                    | <b>AEACNOTH</b>                        |  |
| None   |  |  |
| Concomitant Medication   |  |  |
| Concomitant Procedure  |  |  |
| Outcome  | <b>AEOUT</b>                           | Fatal <input type="checkbox"/><br>Not Recovered/Not Resolved <input type="checkbox"/><br>Recovered/Resolved <input type="checkbox"/><br>Recovered/Resolved with Sequelae <input type="checkbox"/><br>Recovering/Resolving <input type="checkbox"/><br>Unknown <input type="checkbox"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | <b>SUPPAE.QVAL when QNAM = AEOUTSP</b> |  |
| Narrative  | <b>[NOT SUBMITTED]</b>                 |  |

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**Form: Prior/Concomitant Medication and Vaccination Summary**

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|   |                              |
|---|------------------------------|
| Were any prior/concomitant medications and/or vaccinations taken? | Yes <input type="checkbox"/> |
|   | No <input type="checkbox"/>  |

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

**CM = Concomitant and Prior Medications**

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Form: Prior/Concomitant Medication and Vaccination

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**CMCAT = PRIOR MEDICATION or  
CONCOMITANT MEDICATION or  
VACCINATION**

|                                |   |  |
|--------------------------------|---|--|
| Name of Medication             | <b>CMTRT</b>                            |  |
| Prophylaxis                    | <b>SUPPCM.QVAL when QNAM = Cmplx</b>    | Yes <input type="checkbox"/><br>No <input type="checkbox"/>  |
| Indication                     | <b>CMINDC</b>                           |  |
| Dose per administration        | <b>CMDOSE</b>                           |  |
| Dose unit                      | <b>CMDOSU</b>                           | mg <input type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify | <b>SUPPCM.QVAL when QNAM = CMUOTHSP</b> |  |
| Frequency                      | <b>CMDOSFRQ</b>                         | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify | <b>SUPPCM.QVAL when QNAM = CMFOTHSP</b> |  |
| Route of administration        | <b>CMROUTE</b>                          | Oral <input type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>   |

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Form: Prior/Concomitant Medication and Vaccination

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|                |   |
|----------------|---|
|                | Respiratory (Inhalation) <input type="checkbox"/> |
|                | Intralesional <input type="checkbox"/>            |
| <b>CMROUTE</b> | Intraperitoneal <input type="checkbox"/>          |
|                | Nasal <input type="checkbox"/>                    |
|                | Vaginal <input type="checkbox"/>                  |
|                | Rectal <input type="checkbox"/>                   |
|                | Intravenous <input type="checkbox"/>              |
|                | Intravenous Bolus <input type="checkbox"/>        |
|                | Intravenous Drip <input type="checkbox"/>         |
|                | Other <input type="checkbox"/>                    |

---

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 ☐

---

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**Folder: Uniques**

**Form: Concomitant Procedures Summary**

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|  |                              |
|--|------------------------------|
| Were any concomitant procedures performed? | Yes <input type="checkbox"/> |
|  | No <input type="checkbox"/>  |

**If yes, please complete Concomitant Procedures form.**

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Folder: Uniques

**PRCAT = CONCOMITANT PROCEDURES**

Form: Concomitant Procedures

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|   |                |  |
|---|----------------|--|
| Procedure/Surgery date ( <i>dd MMM yyyy</i> ) | <b>PRSTDTC</b> |  |
| Procedure/Surgery                             |                | <b>PRTRT</b>                             |
| Indication                                    |                | Adverse Event <input type="checkbox"/>   |
|   | <b>PRINDC</b>  | Medical History <input type="checkbox"/> |
|   |                | Diagnostic <input type="checkbox"/>      |
|   |                | Other <input type="checkbox"/>           |
| If indication is Other, specify               | <b>PRINDC</b>  |  |

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Folder: Uniques **DSCAT = DISPOSITION EVENT**

Form: Dosing Discontinuation **DSSCAT = STUDY TREATMENT**

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Date of dosing discontinuation (dd MMM yyyy) **[NOT SUBMITTED]**

|   |   |
|---|---|
| Primary reason for dosing discontinuation | AE (specify) <input type="checkbox"/>                                   |
|   | SAE (specify) <input type="checkbox"/>                                  |
|   | Death <input type="checkbox"/>  |
| <b>DSTERM</b>                             | Lost To Follow-up <input type="checkbox"/>                              |
| <b>DSDECOD</b>                            | Physician decision (specify) <input type="checkbox"/>                   |
|   | Pregnancy <input type="checkbox"/>                                      |
|   | Protocol deviation (specify) <input type="checkbox"/>                   |
|   | Study Terminated By Sponsor <input type="checkbox"/>                    |
|   | Withdrawal of consent by participant (specify) <input type="checkbox"/> |
|   | Due to SARS-COV-2 <input type="checkbox"/>                              |
|   | Other <input type="checkbox"/>  |

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify **DSTERM for reason listed above**

**DSSPID, if AE/SAE**

**SUPPDS.QVAL when QNAM=AESPIDX**



**DS = Disposition****DD = Death Details****DM = Demographics**

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Folder: Uniques

**DSCAT = DISPOSITION EVENT**

Form: End of Study / Study Discontinuation

**DSSCAT = END OF STUDY**

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Date of study discontinuation/completion (dd MMM yyyy)

**DSSTDTC**

Reason for discontinuation

AE (specify) ☐SAE (specify) ☐**DSTERM = COMPLETED** Complete ☐**DSDECOD** **DSTERM** Death ☐Lost To Follow-up ☐Physician decision (specify) ☐Pregnancy ☐Protocol deviation (specify) ☐Study Terminated By Sponsor ☐Withdrawal of consent by participant (specify) ☐**DSDECOD = OTHER** Other ☐**DSTERM**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

**SUPPDS.QVAL when QNAM=AESPIDX**

If reason for discontinuation is Death, main cause of death

Adverse event ☐**DSTERM = DEATH****DDTESTCD = DTHCAUS****DDORRES** Unknown ☐**DDTEST = Main cause of death**Other ☐**DSTERM**

If main cause of death is Other, specify

**SUPPDD.QVAL when QNAM = DSDTHSP**

Date of death (dd MMM yyyy)

**DDDTTC****DTHDTC and DTHFL = Y**

Was autopsy performed?

Yes ☐**DDTESTCD = AUTOPERF****DDORRES**No ☐**DDTEST = Autopsy performed**Unknown ☐

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**[NOT SUBMITTED]**

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**Form: Continuing**

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Is the participant continuing to the next visit?

Yes ☐

No ☐

**SC = Subject Characteristics**

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Form: Risk of Exposure

**SCCAT = COVID-19 EXPOSURE**

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| Occupational Risk   | SCSCAT  |  |
|---|---------|--|
| <b>Healthcare workers</b> (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)  | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Emergency Response</b> (e.g., Law enforcement officers, Firefighters, emergency medical service workers)   | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Retail or Restaurant Operations</b> , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Manufacturing &amp; Production Operations</b> with inherent overcrowding (e.g., factory workers, meat/food processing plants)                        | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Warehouse shipping and fulfillment centers</b> and jobs (e.g., Amazon facilities)  | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Transportation and delivery services</b> (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)                                     | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Border Protection and Military Personnel</b> (e.g., TSA, custom and border protection agents, military personnel not social distancing)              | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Personal Care and in-home services</b> (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)                | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Hospitality and Tourism Workers</b> (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)  | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Pastoral, Social or Public Health Workers</b> requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Educators and Students</b> (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)                  | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| <b>Other</b>  | SCORRES | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                              |
| Specify   | SCORRES | <b>SUPPSC.QVAL when QNAM = SCORRS1 / SCORRS2 when text &gt; 200, split into multiple</b> |
| <b>Location and Living Circumstances Risk</b> (check all that apply)  | SCSCAT  |  |
| <b>No Risk Identified</b>   | SCORRES |  |
| <b>Resides in Nursing Home or Assisted Living Facility</b>  | SCORRES |  |
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)            | SCORRES |  |

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**SC = Subject Characteristics**

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Folder: Uniques

Form: Risk of Exposure

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**SCCAT = COVID-19 EXPOSURE****Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)**SCORRES****SCTEST****Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)**SCORRES****Resides in a single family home** (i.e., detached housing)**SCORRES****Other****SCORRES****Specify****SUPPSC.QVAL when QNAM = SCORRS1 / SCORRS2  
when text > 200, split into multiple**

**SV = Subject Visits**

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Folder: Uniques

Form: COVID-19 Contact

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|  |                             |   |
|--|-----------------------------|---|
| Date of Contact                                  | <b>SVSTDTC</b>              |   |
| Time of Contact                                  |                             |   |
| Type of Contact                                  | <b>SVCNTMOD = IN PERSON</b> | <input type="checkbox"/> Clinic Visit - Scheduled     |
|  |                             | <input type="checkbox"/> Clinical Visit - Unscheduled |
|  | <b>SVCNTMOD = TELEPHONE</b> | <input type="checkbox"/> Safety Call                  |
|  |                             | <input type="checkbox"/> Convalescent Tele-visit      |
| Has the subject reported symptoms of SARS-COV-2? | <b>SVEPCHGI = Y</b>         | Yes <input type="checkbox"/>                          |
|  |                             | No <input type="checkbox"/>                           |

**FA = Findings About**

**CE = Clinical Events**

**FACAT = EFFICACY**

**FASCAT= COVID-19**

*Note: Topline records created in Clinical Events by collapsing diary records, per Vaccine Therapeutic Area Guide v1.1*

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

Folder: Uniques

Form: Symptom Log

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**CECAT = EFFICACY**

**CESCAT= COVID-19**

**CEPRES = Y**

Symptom Day

**FATPT**

**CETPT**

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

**CE = Clinical Events**

for Topline records

**FA = Findings About****FACAT = EFFICACY****FASCAT= COVID-19****VS = Vital Signs****VSCAT = EFFICACY****VSSCAT = COVID-19****FATESTCD/FATEST = SEV/ Severity/Intensity**

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

Folder: Uniques

Form: Symptom Log

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**CECAT = EFFICACY****CESCAT= COVID-19****CEPRES = Y**

Day 34 ☐

Day 35 ☐

Day 36 ☐

Day 37 ☐

Day 38 ☐

Day 39 ☐

Day 40 ☐

Date **CEDTC** **FADTC** **VSDTC**Assessment Not Done **FASTAT = NOT DONE**O2 Saturation **CEOCCUR= Y when O2SAT <= 93%** **VSTESTCD = OXYSAT****CETERM = Oxygen Saturation of SpO2<=93% on room air at sea level** **VSORRES/VSORRESU**

Temperature

**VSTESTCD = TEMP** C ☐**VSORRES/VSORRESU** F ☐**CEOCCUR= Y when Temp >= 38C**

Chills

**FAOBJ** **CETERM**None ☐**CEOCCUR= N**Mild ☐**CESEV** **FAORRES** Moderate ☐Severe ☐**CESTAT = NOT DONE** **FASTAT = NOT DONE** Not Done ☐

Cough

**FAOBJ** **CETERM**None ☐**CEOCCUR= N**Mild ☐**CESEV** **FAORRES** Moderate ☐Severe ☐**CESTAT = NOT DONE** **FASTAT = NOT DONE** Not Done ☐

Shortness of Breath

**FAOBJ** **CETERM**None ☐**CEOCCUR= N**Mild ☐**CESEV** **FAORRES** Moderate ☐Severe ☐**CESTAT = NOT DONE** **FASTAT = NOT DONE** Not Done ☐

Difficulty Breathing

**FAOBJ** **CETERM**None ☐**CEOCCUR= N**Mild ☐**CESEV** **FAORRES** Moderate ☐Severe ☐

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**CE = Clinical Events****for Topline records****FA = Findings About****FACAT = EFFICACY****FASCAT= COVID-19****FATESTCD/FATEST = SEV/ Severity/Intensity**

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Folder: Uniques

Form: Symptom Log

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**CECAT = EFFICACY****CESCAT= COVID-19****CEPRES = Y**

|                            |                          |                             |                                |                   |
|----------------------------|--------------------------|-----------------------------|--------------------------------|-------------------|
|                            |                          | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| Fatigue                    |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               | <b>CETERM</b>            |                             | Mild <input type="radio"/>     |                   |
|                            |                          | <b>CESEV</b> <b>FAORRES</b> | Moderate <input type="radio"/> |                   |
|                            |                          |                             | Severe <input type="radio"/>   |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| Muscle Aches (Myalgia)     |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>FAOBJ = Myalgia</b>     |                          |                             | Mild <input type="radio"/>     |                   |
| <b>CETERM = Myalgia</b>    |                          | <b>CESEV</b> <b>FAORRES</b> | Moderate <input type="radio"/> |                   |
|                            |                          |                             | Severe <input type="radio"/>   |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| Body Aches                 |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               | <b>CETERM</b>            |                             | Mild <input type="radio"/>     |                   |
|                            |                          | <b>CESEV</b> <b>FAORRES</b> | Moderate <input type="radio"/> |                   |
|                            |                          |                             | Severe <input type="radio"/>   |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| Headache                   |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               | <b>CETERM</b>            |                             | Mild <input type="radio"/>     |                   |
|                            |                          | <b>CESEV</b> <b>FAORRES</b> | Moderate <input type="radio"/> |                   |
|                            |                          |                             | Severe <input type="radio"/>   |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| New Loss of Taste          |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               | <b>CETERM</b>            |                             | Mild <input type="radio"/>     |                   |
|                            |                          | <b>CESEV</b> <b>FAORRES</b> | Moderate <input type="radio"/> |                   |
|                            |                          |                             | Severe <input type="radio"/>   |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| New Loss of Smell          |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               | <b>CETERM</b>            |                             | Mild <input type="radio"/>     |                   |
|                            |                          | <b>CESEV</b> <b>FAORRES</b> | Moderate <input type="radio"/> |                   |
|                            |                          |                             | Severe <input type="radio"/>   |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b>    | Not Done <input type="radio"/> |                   |
| <hr/>                      |                          |                             |                                |                   |
| Nasal Congestion           |                          |                             | None <input type="radio"/>     | <b>CEOCCUR= N</b> |
| <b>CETERM</b> <b>FAOBJ</b> |                          |                             |                                |                   |

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**CE = Clinical Events**

**for Topline records**

**FA = Findings About**

**FACAT = EFFICACY**

**FASCAT= COVID-19**

**FATESTCD/FATEST = SEV/ Severity/Intensity**

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Folder: Uniques

Form: Symptom Log

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**CECAT = EFFICACY**

**CESCAT= COVID-19**

**CEPRES = Y**

|                            |                          |                          |          |                          |                   |
|----------------------------|--------------------------|--------------------------|----------|--------------------------|-------------------|
|                            | <b>CESEV</b>             | <b>FAORRES</b>           | Mild     | <input type="checkbox"/> |                   |
|                            |                          |                          | Moderate | <input type="checkbox"/> |                   |
|                            |                          |                          | Severe   | <input type="checkbox"/> |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b> | Not Done | <input type="checkbox"/> |                   |
| Runny Nose (Rhinorrhea)    |                          |                          | None     | <input type="checkbox"/> | <b>CEOCCUR= N</b> |
| <b>FAOBJ = Rhinorrhea</b>  |                          |                          | Mild     | <input type="checkbox"/> |                   |
| <b>CETERM = Rhinorrhea</b> | <b>CESEV</b>             | <b>FAORRES</b>           | Moderate | <input type="checkbox"/> |                   |
|                            |                          |                          | Severe   | <input type="checkbox"/> |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b> | Not Done | <input type="checkbox"/> |                   |
| Nausea                     | <b>CETERM</b>            |                          | None     | <input type="checkbox"/> | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               |                          |                          | Mild     | <input type="checkbox"/> |                   |
|                            | <b>CESEV</b>             | <b>FAORRES</b>           | Moderate | <input type="checkbox"/> |                   |
|                            |                          |                          | Severe   | <input type="checkbox"/> |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b> | Not Done | <input type="checkbox"/> |                   |
| Vomiting                   | <b>CETERM</b>            |                          | None     | <input type="checkbox"/> | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               |                          |                          | Mild     | <input type="checkbox"/> |                   |
|                            | <b>CESEV</b>             | <b>FAORRES</b>           | Moderate | <input type="checkbox"/> |                   |
|                            |                          |                          | Severe   | <input type="checkbox"/> |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b> | Not Done | <input type="checkbox"/> |                   |
| Diarrhea                   | <b>CETERM</b>            |                          | None     | <input type="checkbox"/> | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               |                          |                          | Mild     | <input type="checkbox"/> |                   |
|                            | <b>CESEV</b>             | <b>FAORRES</b>           | Moderate | <input type="checkbox"/> |                   |
|                            |                          |                          | Severe   | <input type="checkbox"/> |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b> | Not Done | <input type="checkbox"/> |                   |
| Sore Throat                | <b>CETERM</b>            |                          | None     | <input type="checkbox"/> | <b>CEOCCUR= N</b> |
| <b>FAOBJ</b>               |                          |                          | Mild     | <input type="checkbox"/> |                   |
|                            | <b>CESEV</b>             | <b>FAORRES</b>           | Moderate | <input type="checkbox"/> |                   |
|                            |                          |                          | Severe   | <input type="checkbox"/> |                   |
|                            | <b>CESTAT = NOT DONE</b> | <b>FASTAT = NOT DONE</b> | Not Done | <input type="checkbox"/> |                   |

**MB = Microbiology Specimen**

v13.005 Publish Checks to Prod CRF Version 1725: Unique

Folder: Uniques

Form: COVID Diagnostic Test

Generated On: 30 Apr 2021 19:52:48

**MBCAT = SARS-CoV-2****MBTESTCD = SARSCOV2****MBMETHOD = RT-PCR**

Date of Visit

**SUPPMB.QVAL when QNAM=LDTVISDT**

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

**MBSTAT = NOT DONE**Yes ☐No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

**MBORRES**Yes ☐No ☐

Date of Test

**MBDTC**

Type of Test Performed

Nasopharyngeal Swab ☐Nasal Swab ☐**MBSPEC**Saliva Test ☐Other ☐

Other, specify

**SUPPMB.QVAL when QNAM=LDTTESTO**

Was this diagnostic test performed at a lab other than the Study Central Lab?

**[NOT SUBMITTED]**Yes ☐No ☐

If yes, provide lab information below

Lab/ Institution Test Performed

**MBNAM**

CLIA Certified?

**SUPPMB.QVAL when QNAM=LDTCLIA**Yes ☐No ☐

**MBCAT = SARS-CoV-2****MBTESTCD = SARSCOV2**

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

Folder: Uniques

Form: Saliva Collection

**MBSPEC = SALIVA**

Generated On: 30 Apr 2021 19:52:48

|       |        |                                  |
|-------|--------|----------------------------------|
| Visit | Day 3  | <input checked="" type="radio"/> |
|       | Day 5  | <input type="radio"/>            |
|       | Day 7  | <input type="radio"/>            |
|       | Day 9  | <input type="radio"/>            |
|       | Day 14 | <input type="radio"/>            |
|       | Day 21 | <input type="radio"/>            |
|       | Day 28 | <input type="radio"/>            |

|                       |                        |                       |
|-----------------------|------------------------|-----------------------|
| Was Saliva Collected? | Yes                    | <input type="radio"/> |
|                       | No                     | <input type="radio"/> |
|                       | NA (COVID-19 Negative) | <input type="radio"/> |

|                    |              |
|--------------------|--------------|
| Date of Collection | <b>MBDTC</b> |
|--------------------|--------------|

|       |        |                                  |
|-------|--------|----------------------------------|
| Visit | Day 3  | <input type="radio"/>            |
|       | Day 5  | <input checked="" type="radio"/> |
|       | Day 7  | <input type="radio"/>            |
|       | Day 9  | <input type="radio"/>            |
|       | Day 14 | <input type="radio"/>            |
|       | Day 21 | <input type="radio"/>            |
|       | Day 28 | <input type="radio"/>            |

|                       |                        |                       |
|-----------------------|------------------------|-----------------------|
| Was Saliva Collected? | Yes                    | <input type="radio"/> |
|                       | No                     | <input type="radio"/> |
|                       | NA (COVID-19 Negative) | <input type="radio"/> |

|                    |              |
|--------------------|--------------|
| Date of Collection | <b>MBDTC</b> |
|--------------------|--------------|

|       |        |                                  |
|-------|--------|----------------------------------|
| Visit | Day 3  | <input type="radio"/>            |
|       | Day 5  | <input type="radio"/>            |
|       | Day 7  | <input checked="" type="radio"/> |
|       | Day 9  | <input type="radio"/>            |
|       | Day 14 | <input type="radio"/>            |
|       | Day 21 | <input type="radio"/>            |
|       | Day 28 | <input type="radio"/>            |

|                       |                        |                       |
|-----------------------|------------------------|-----------------------|
| Was Saliva Collected? | Yes                    | <input type="radio"/> |
|                       | No                     | <input type="radio"/> |
|                       | NA (COVID-19 Negative) | <input type="radio"/> |

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Version 1725 (1822)

**MBCAT = SARS-CoV-2****MBTESTCD = SARSCOV2**

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

Folder: Uniques

Form: Saliva Collection

**MBSPEC = SALIVA**

Generated On: 30 Apr 2021 19:52:48

|                    |              |   |
|--------------------|--------------|---|
| Date of Collection | <b>MBDTC</b> |   |
| Visit              |              | Day 3 <input type="checkbox"/>            |
|                    |              | Day 5 <input type="checkbox"/>            |
|                    |              | Day 7 <input type="checkbox"/>            |
|                    | <b>MBTPT</b> | Day 9 <input checked="" type="checkbox"/> |
|                    |              | Day 14 <input type="checkbox"/>           |
|                    |              | Day 21 <input type="checkbox"/>           |
|                    |              | Day 28 <input type="checkbox"/>           |

|                                   |                          |   |
|-----------------------------------|--------------------------|---|
| Was Saliva Collected?             |                          | Yes <input type="checkbox"/>                    |
|                                   | <b>MBSTAT = NOT DONE</b> | No <input type="checkbox"/>                     |
| <b>MBREASND=COVID-19 NEGATIVE</b> | <b>MBSTAT = NOT DONE</b> | NA (COVID-19 Negative) <input type="checkbox"/> |

|                    |              |  |
|--------------------|--------------|--|
| Date of Collection | <b>MBDTC</b> |  |
| Visit              |              | Day 3 <input type="checkbox"/>             |
|                    |              | Day 5 <input type="checkbox"/>             |
|                    |              | Day 7 <input type="checkbox"/>             |
|                    |              | Day 9 <input type="checkbox"/>             |
|                    | <b>MBTPT</b> | Day 14 <input checked="" type="checkbox"/> |
|                    |              | Day 21 <input type="checkbox"/>            |
|                    |              | Day 28 <input type="checkbox"/>            |

|                                   |                          |   |
|-----------------------------------|--------------------------|---|
| Was Saliva Collected?             |                          | Yes <input type="checkbox"/>                    |
|                                   | <b>MBSTAT = NOT DONE</b> | No <input type="checkbox"/>                     |
| <b>MBREASND=COVID-19 NEGATIVE</b> | <b>MBSTAT = NOT DONE</b> | NA (COVID-19 Negative) <input type="checkbox"/> |

|                    |              |  |
|--------------------|--------------|--|
| Date of Collection | <b>MBDTC</b> |  |
| Visit              |              | Day 3 <input type="checkbox"/>             |
|                    |              | Day 5 <input type="checkbox"/>             |
|                    |              | Day 7 <input type="checkbox"/>             |
|                    |              | Day 9 <input type="checkbox"/>             |
|                    |              | Day 14 <input type="checkbox"/>            |
|                    | <b>MBTPT</b> | Day 21 <input checked="" type="checkbox"/> |
|                    |              | Day 28 <input type="checkbox"/>            |

|                       |                          |                              |
|-----------------------|--------------------------|------------------------------|
| Was Saliva Collected? |                          | Yes <input type="checkbox"/> |
|                       | <b>MBSTAT = NOT DONE</b> | No <input type="checkbox"/>  |

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Version 1725 (1822)

**MBCAT = SARS-CoV-2**

**MBTESTCD = SARSCOV2**

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

Folder: Uniques

Form: Saliva Collection

Generated On: 30 Apr 2021 19:52:48

**MBSPEC = SALIVA**

**MBREASND=COVID-19 NEGATIVE** **MBSTAT = NOT DONE** NA (COVID-19 Negative) ☐

Date of Collection **MBDTC** \_\_\_\_\_

Visit \_\_\_\_\_

Day 3 ☐

Day 5 ☐

Day 7 ☐

Day 9 ☐

Day 14 ☐

Day 21 ☐

**MBTPT** Day 28 ☒

Was Saliva Collected? \_\_\_\_\_

Yes ☐

**MBSTAT = NOT DONE** No ☐

**MBREASND=COVID-19 NEGATIVE** **MBSTAT = NOT DONE** NA (COVID-19 Negative) ☐

Date of Collection **MBDTC** \_\_\_\_\_

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

Folder: Uniques

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 30 Apr 2021 19:52:48

|  |   |         |
|--|---|---------|
| Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection? | Yes <input type="checkbox"/>                    | FAORRES |
|  | No <input type="checkbox"/>                     |         |
|  | NA (COVID-19 Negative) <input type="checkbox"/> |         |
| <div>ISREASND =COVID-19 NEGATIVE</div> <div>ISSTAT = NOT DONE</div>        |   |         |
| Date of Collection   | <div>ISDTC</div>                                |         |

**CE = Clinical Events****for Topline records****CECAT = EFFICACY****CESCAT = COVID-19 SEVERITY****FA = Findings About****FACAT = EFFICACY****FASCAT = COVID-19 SEVERITY****FATESTCD/FATEST = OCCUR/Occurrence Indicator****VS = Vital Signs****VSCAT = EFFICACY****VSSCAT = COVID-19 SEVERITY**

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

Folder: Uniques

Form: Covid-19 Severity Assessment

Generated On: 30 Apr 2021 19:52:48

**CEPRES = Y**Did the subject have Respiratory Rates  $\geq 30$  per Minute?**FAOBJ****CEOCCUR**Yes ☐  
No ☐**FAORRES****CETERM = Respiratory Rates  $\geq 30$  per Minute**

If Yes, provide:

Start Date

**CESTDTC****FADTC / SUPPFA.QVAL when QNAM = FAEVDTC****VSDTC**

End Date

**CEDTC/ CEENDTC****FAENDTC**

Respiratory Rate

Fixed Unit: /minute

**VSORRES when VSTESTCD = RESP****VSORRESU**Did the subject have Heart Rate  $\geq 125$  beats per minute**FAOBJ****CEOCCUR**Yes ☐  
No ☐**FAORRES****CETERM = Heart Rate  $\geq 125$  per Minute**

If Yes, provide:

Start Date

**CESTDTC****FADTC / SUPPFA.QVAL when QNAM = FAEVDTC****VSDTC**

End Date

**CEDTC/ CEENDTC****FAENDTC**

Heart Rate

Fixed Unit: BPM

**VSORRES when VSTESTCD = HR****VSORRESU**Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level?**FAOBJ****CEOCCUR**Yes ☐  
No ☐**FAORRES****CETERM = Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level**

If Yes, provide:

Start Date

**CESTDTC****FADTC / SUPPFA.QVAL when QNAM = FAEVDTC****VSDTC**

End Date

**CEDTC/ CEENDTC****FAENDTC**

Oxygen Saturation

Fixed Unit: %

**VSORRES when VSTESTCD = OXYSAT****VSORRESU**Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg?**FAOBJ****CEOCCUR**Yes ☐  
No ☐**FAORRES****CETERM = PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mmHg**

If Yes, provide:

Start Date

**CESTDTC****FADTC / SUPPFA.QVAL when QNAM = FAEVDTC****VSDTC**

End Date

**CEDTC/ CEENDTC****FAENDTC**PaO<sub>2</sub>

Fixed Unit: mmHg

**VSORRES when VSTESTCD = PaO<sub>2</sub>/FIO<sub>2</sub>****VSORRESU**

Did the subject have Respiratory failure?

**FAOBJ****CEOCCUR**Yes ☐  
No ☐**FAORRES****CETERM = Respiratory Failure**

Start Date

**CEDTC/ CESTDTC****FADTC / SUPPFA.QVAL when QNAM = FAEVDTC**

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Version 1725 (1822)

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**CE = Clinical Events****FA = Findings About****PR = Procedures****CECAT = EFFICACY****FACAT = EFFICACY****PRCAT = EFFICACY****CESCAT= COVID-19 SEVERITY****FASCAT = COVID-19 SEVERITY****PRSCAT = COVID-19 SEVERITY****FATESTCD/FATEST = OCCUR/Occurrence Indicator**

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

Folder: Uniques

Form: Covid-19 Severity Assessment

Generated On: 30 Apr 2021 19:52:48

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Yes ☐No ☐**CETERM= Acute Respiratory Distress Syndrome (ARDS)****FAOBJ****CEOCCUR****FAORRES**

Start Date

**FADTC****CEDTC/CESTDTC**

If Yes to either Did subject require any of the following:

Ventilator Support:

**PRGRPID**

High-Flow Oxygen?

Yes ☐No ☐**PRTRT = High-Flow Oxygen****PROCCUR**

Start Date

**PRSTDTC**

End Date

**PRENDTC**

Non-Invasive Ventilation?

Yes ☐No ☐**PRTRT = Non-Invasive Ventilation****PROCCUR**

Start Date

**PRSTDTC**

End Date

**PRENDTC**

Mechanical Ventilation?

Yes ☐No ☐**PRTRT = Mechanical Ventilation****PROCCUR**

Start Date

**PRSTDTC**

End Date

**PRENDTC**

ECMO?

Yes ☐No ☐**PRTRT = ECMO****PROCCUR**

Start Date

**PRSTDTC**

End Date

**PRENDTC**

Evidence of Shock:

Systolic Blood Pressure &lt; 90 mmHg, Diastolic Blood Pressure &lt; 60

mmHg

Yes ☐No ☐**FAOBJ****CETERM****CEOCCUR****FAORRES**

Start Date

**CESTDTC****FADTC**

End Date

**CEDTC/CEENDTC****FAENDTC**

Evidence of Shock Requires

Yes ☐No ☐**FAOBJ**

Vasopressors

**CETERM****CEOCCUR****FAORRES**

Start Date

**CESTDTC****FADTC**

End Date

**CEDTC/CEENDTC****FAENDTC**

Acute Renal Dysfunction?

Yes ☐No ☐**FAOBJ****CETERM= Acute Renal Dysfunction****CEOCCUR****FAORRES**

v13.005 Publish Checks to Prod CRF

Version 1725 (1822)

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**CE = Clinical Events****FA = Findings About****HO = Healthcare Encounters****CECAT = EFFICACY****FACAT = EFFICACY****HOCAT = EFFICACY****CESCAT= COVID-19 SEVERITY****FASCAT = COVID-19 SEVERITY****HOSCAT = COVID-19 SEVERITY****FATESTCD/FATEST = OCCUR/Occurrence Indicator**

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

Folder: Uniques

Form: Covid-19 Severity Assessment

Generated On: 30 Apr 2021 19:52:48

Start Date

**FADTC****CEDTC/CESTDTC****FAOBJ**

Hepatic Dysfunction?

**CETERM = Hepatic Dysfunction****FAORRES**Yes ☐No ☐**CEOCCUR**

Start Date

**FADTC****CEDTC/CESTDTC****FAOBJ**

Neurologic Dysfunction?

**CETERM = Neurologic Dysfunction****FAORRES**Yes ☐No ☐**CEOCCUR**

Start Date

**FADTC****CEDTC/CESTDTC**

Evidence of Pneumonia:

Clinical Evidence

**FAOBJ = Clinical Evidence of Pneumonia****CETERM = Clinical Evidence of Pneumonia****FAORRES**Yes ☐No ☐**CEOCCUR**

Date of Assessment

**FADTC****CEDTC/CESTDTC**

Radiographical Evidence

**FAOBJ = Radiographical Evidence of Pneumonia****CETERM = Radiographical Evidence of Pneumonia****FAORRES**Yes ☐No ☐**CEOCCUR**

Date of Assessment

**FADTC****CEDTC/CESTDTC****HOPRESP = Y**

Admission to an intensive care unit due to SARS-CoV-2

**HOTERM****HOCCUR = Y**Yes ☐**CESHOSP=Y****HODECOD = ICU****HOCCUR = N**No ☐

Start Date

**HOSTDTC**

End Date

**HOENDTC**

**[NOT SUBMITTED]**

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

**Folder: Uniques**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 30 Apr 2021 19:52:48**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

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

Folder: Uniques

Form: COVID-19 Impact

Generated On: 30 Apr 2021 19:52:48

**SVEPCHGI = Y**

|              |                 |                          |
|--------------|-----------------|--------------------------|
| Visit        | Screening       | <input type="checkbox"/> |
|              | Visit 1 Day 1   | <input type="checkbox"/> |
|              | Visit 2 Day 29  | <input type="checkbox"/> |
| <b>VISIT</b> | Visit 3 Day 57  | <input type="checkbox"/> |
|              | Visit 4 Day 209 | <input type="checkbox"/> |
|              | Visit 5 Day 394 | <input type="checkbox"/> |
|              | Visit 6 Day 759 | <input type="checkbox"/> |

**Case Report Form**

|  |   |
|--|---|
| Visit Date   |   |
| Demographics   |   |
| Enrollment   |   |
| Inclusion/Exclusion Criteria Summary                                       |   |
| Inclusion/Exclusion Criteria   |   |
| Medical History Summary  | <b>SVUPDES</b>                            |
| Medical History  | <b>Concatenate all missed assessments</b> |
| Vital Signs  |   |
| Vital Signs - Dosing   |   |
| Physical Examination   |   |
| Central Laboratory - Nasopharyngeal Swab                                   |   |
| Childbearing Potential   |   |
| Pregnancy Test   |   |
| Randomization  |   |
| Exposure   |   |
| Immunogenicity Assessment  |   |
| Saliva Collection  |   |
| COVID Diagnostic Test  |   |
| Symptom Log  |   |
| Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection |   |
| COVID-19 Severity Assessment   |   |
| COVID-19 Contact   |   |
| Risk of Exposure   |   |
| Safety Call  |   |
| Dosing Discontinuation   |   |
| End of Study / Study Discontinuation                                       |   |

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

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

**CE = Clinical Events****for Topline records****VS = Vital Signs****VSCAT = REACTOGENICITY****VSSCAT = SYSTEMIC**Note: "Fever" is mapped into  
CE if within 7-day window.**CECAT = REACTOGENICITY****CESCAT = SYSTEMIC****CEPRES = Y**

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

Folder: Uniques

Form: Temperature\_Day

Generated On: 30 Apr 2021 19:52:48

**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 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?**VSSTAT = NOT DONE**  
Missing records will also be  
considered as **NOT DONE**Yes ☐  
No ☐Please record your **TEMPERATURE** in °F

Fixed Unit: °F

**VSTEST = Temperature****VSORRES / VSORRESU when VSTESTCD = TEMP**Was any **MEDICATION TAKEN** today for pain or fever?**SUPPVS.QVAL when QNAM = MEDTAK**Yes ☐  
No ☐**CEOCCUR= Y when Temp >= 38C**

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

**CEDTC****VSDTC****[NOT SUBMITTED]**

PC Open Date &amp; Time

**[NOT SUBMITTED]**

PC Close Date &amp; Time

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CE = Clinical Events

FA = Findings About

for Topline records

FASCAT = ADMINISTRATION SITE

Note: Mapped to CE/FACE,  
if within 7-day window,  
or else mapped to FAAE

CECAT = REACTOGENICITY

CESCAT = ADMINISTRATION SITE

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

Folder: Uniques

Form: Injection Site\_Day

CEPRES = Y

Generated On: 30 Apr 2021 19:52:48

TIMEPOINT

FATPT

Please record - PAIN AT INJECTION SITE.

FAOBJ

CETERM

CEOCCUR = N None

Please select one response below

Does not interfere with activity

CELNKGPR =  
1030/2030

FAORRES when FATESTCD = SEV

Repeated use of over-the-counter

FALNKGPR =  
1030/2030

CEOCCUR = Y

pain reliever > 24 hours or

interferes with activity

Any use of prescription pain

reliever or prevents daily activity

Is there any REDNESS AT INJECTION SITE?

FAOBJ = Erythema

CEOCCUR = Yes

CETERM = Erythema

FAORRES when FATESTCD = OCCUR

No

CELNKGPR =  
1040/2040

Please record - REDNESS AT INJECTION SITE (in mm)

FAORRESU

Measure the largest size across any injection site redness  
ruler provided.

FAORRES when FATESTCD = LDIAM

Is there any SWELLING/HARDNESS AT INJECTION SITE?

FAOBJ

CEOCCUR = Yes

CETERM

FAORRES when FATESTCD = OCCUR

No

CELNKGPR =  
1050/2050

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

Please record - UNDERARM GLAND SWELLING OR  
TENDERNESS.

FAOBJ

CETERM

CEOCCUR = N None

Please select one response below

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

FAORRES when FATESTCD = SEV

CELNKGPR =  
1060/2060

FALNKGPR =  
1060/2060

PC Time Stamp

FADTC

CEDTC

PC Open Date & Time

[NOT SUBMITTED]

PC Close Date & Time

[NOT SUBMITTED]

**CE = Clinical Events****FA = Findings About****HO = Healthcare Encounters**Note: Mapped to CE/FACE,  
if within 7-day window,  
or else mapped to FAAE

for Topline records

v13.005 Publish Checks to Prod CRF Vers

Folder: Uniques

Form: General\_Day

Generated On: 30 Apr 2021 19:52:48

**CECAT = REACTOGENICITY****FACAT = REACTOGENICITY****CESCAT = SYSTEMIC****FASCAT = SYSTEMIC****CEPRES = Y****TIMEPOINT****FATPT****CELNKGPR = 1070/2070****HEADACHE****FAOBJ****CEOCCUR = N**None ☐**FALNKGPR = 1070/2070****CETERM**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 ☐**FAORRES when FATESTCD = SEV****CEOCCUR = Y****FATIGUE****CELNKGPR = 1080/2080****CETERM****FAOBJ****CEOCCUR = Y**None ☐No interference with activity ☐Some interference with activity ☐Significant; prevents daily ☐activity ☐**FALNKGPR = 1080/2080****FAORRES when FATESTCD = SEV****MUSCLE ACHES ALL OVER BODY****CELNKGPR = 1090/2090****CETERM = Myalgia****FAOBJ = Myalgia****CEOCCUR = Y****CEOCCUR = N**None ☐No interference with activity ☐Some interference with activity ☐Significant; prevents daily ☐activity ☐**FALNKGPR = 1090/2090****FAORRES when FATESTCD = SEV****JOINT ACHES IN SEVERAL JOINTS****CELNKGPR = 1100/2100****CEOCCUR = Y****CEOCCUR = N**None ☐No interference with activity ☐Some interference with activity ☐Significant; prevents daily ☐activity ☐**FALNKGPR = 1100/2100****FAORRES when FATESTCD = SEV****NAUSEA/VOMITING****CELNKGPR = 1110/2110****CETERM****FAOBJ****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 ☐**FALNKGPR = 1110/2110****FAORRES when FATESTCD = SEV****CEOCCUR = Y****CHILLS****CELNKGPR = 1120/2120****CETERM****FAOBJ****CEOCCUR = Y****CEOCCUR = N**None ☐No interference with activity ☐Some interference with activity ☐not requiring medical attention ☐Prevents daily activity and ☐requires medical attention ☐**FALNKGPR = 1120/2120****FAORRES when FATESTCD = SEV****HOTERM = MEDICALLY ATTENDED****HODECOD = MAAE****HOPRESP = Y**Did you receive any **MEDICAL ATTENTION** (doctor visit,  
other) for any illness or symptoms?**HOCCUR=N** No ☐**SUPPFA.QVAL when QNAM= MAAEFL**

v13.005 Publish Checks to Prod CRF

Version 1725 (1822)

**SUPPCE.QVAL when QNAM=MAAEFL**

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HO = Healthcare Encounters

FA = Findings About

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FACAT = REACTOGENICITY

FASCAT = SYSTEMIC

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HOCAT = EDIARY

HOOCCUR = Y

Yes☐

PC Time stamp

HOSTDTC

HOENDTC

FADTC

PC Open Date & Time

[NOT SUBMITTED]

PC Close Date & Time

[NOT SUBMITTED]



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

Folder: Uniques

Form: Injection Pain\_Day

Generated On: 30 Apr 2021 19:52:48

FACAT = REACTOGENICITY

FASCAT = ADMINISTRATION SITE

FALNKGRP = 1030/2030

|   |                             |   |
|---|-----------------------------|---|
| TIMEPOINT                               | FATPT                       |   |
| Please record - PAIN AT INJECTION SITE. |                             |   |
| Please select one response below        |                             |   |
|   | FAOBJ                       | None <input type="radio"/>  |
|   |                             | Does not interfere with activity <input type="radio"/>  |
|   |                             | Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity <input type="radio"/> |
|   | FAORRES when FATESTCD = SEV | Any use of prescription pain reliever or prevents daily activity <input type="radio"/>                      |
| PC Time Stamp                           | FADTC                       |   |
| PC Open Date & Time                     |                             | [NOT SUBMITTED]   |
| PC Close Date & Time                    |                             | [NOT SUBMITTED]   |

**FA = Findings About**

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Folder: Uniques

Form: Redness\_Day

Generated On: 30 Apr 2021 19:52:48

**FACAT = REACTOGENICITY**

**FASCAT = ADMINISTRATION SITE**

**FALNKGRP = 1030/2030**

TIMEPOINT **FATPT**

Is there any **REDNESS AT INJECTION SITE?** **FAORRES when FATESTCD = OCCUR** Yes ☐  
**FAOBJ** No ☐

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

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]**

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

Folder: Uniques

**FACAT = REACTOGENICITY****FASCAT = ADMINISTRATION SITE**

Form: Swelling\_Day

Generated On: 30 Apr 2021 19:52:48

**FALNKGRP = 1050/2050****TIMEPOINT****FATPT**Is there any **SWELLING/HARDNESS AT INJECTION SITE?**Yes ☐**FAOBJ****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 &amp; Time

**[NOT SUBMITTED]**

PC Close Date &amp; Time

**[NOT SUBMITTED]**

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

Folder: Uniques

**FACAT = REACTOGENICITY****FASCAT = SYSTEMIC**

Form: Headache\_Day

Generated On: 30 Apr 2021 19:52:48

**FALNKGRP = 1070/2070****TIMEPOINT****FATPT**

Select one response below to indicate the intensity of your

None ☐**HEADACHE**No interference with activity ☐**FAOBJ**Repeated use of over-the-counter ☐pain reliever > 24 hours or some ☐**FAORRES when FATESTCD = SEV**

interference with activity

Any use of prescription pain ☐

reliever or prevents daily activity

PC Time Stamp

**FADTC**

PC Open Date &amp; Time

**[NOT SUBMITTED]**

PC Close Date &amp; Time

**[NOT SUBMITTED]**

**FACAT = REACTOGENICITY****FASCAT = SYSTEMIC**

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

Folder: Uniques

Form: Fatigue\_Day

**FALNKGRP = 1080/2080**

Generated On: 30 Apr 2021 19:52:48

**TIMEPOINT** **FATPT**

Select one response below to indicate the intensity of your

None ☐**FATIGUE**No interference with activity ☐**FAOBJ**Some interference with activity ☐**FAORRES when FATESTCD = SEV**Significant; prevents daily activity ☐

PC Time Stamp

**FADTC**

PC Open Date &amp; Time

**[NOT SUBMITTED]**

PC Close Date &amp; Time

**[NOT SUBMITTED]**

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

Folder: Uniques

**FASCAT = SYSTEMIC**

**FACAT = REACTOGENICITY**

Form: MuscleAche\_Day

**FALNKGRP = 1090/2090**

Generated On: 30 Apr 2021 19:52:48

TIMEPOINT **FATPT**

Select one response below to indicate the intensity of your **MUSCLE** None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

**FAOBJ = Myalgia**

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**

**FACAT = REACTOGENICITY**

**FASCAT = SYSTEMIC**

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

Folder: Uniques

Form: JointsAche\_Day

Generated On: 30 Apr 2021 19:52:48

**FALNKGRP = 1100/2100**

TIMEPOINT **FATPT**

Select one response below to indicate the intensity of your **JOINT** None ☐

**ACHES IN SEVERAL JOINTS**

**FAOBJ = Arthralgia**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

**FAORRES when FATESTCD = SEV**

PC Time stamp **FADTC** **[NOT SUBMITTED]**

PC Open Date & Time **[NOT SUBMITTED]**

PC Close Date & Time **[NOT SUBMITTED]**

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

Folder: Uniques

**FASCAT = SYSTEMIC**

**FACAT = REACTOGENICITY**

Form: Nausea\_Day

**FALNKGRP = 1110/2110**

Generated On: 30 Apr 2021 19:52:48

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]**



**FA = Findings About**

**FACAT = REACTOGENICITY**

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

**FASCAT = SYSTEMIC**

Folder: Uniques

Form: Chills\_Day

Generated On: 30 Apr 2021 19:52:48

**FALNKGRP = 1120/2120**

| TIMEPOINT   | FATPT   |
|---|---|
| Select one response below to indicate the intensity of <b>CHILLS</b> you are experiencing |   |
|   | <b>FAOBJ</b>  |
|   | None <input type="radio"/>  |
|   | No interference with activity <input type="radio"/>                                   |
|   | Some interference with activity not requiring medical attention <input type="radio"/> |
|   | Prevents daily activity and requires medical attention <input type="radio"/>          |
|   | <b>FAORRES when FATESTCD = SEV</b>  |
| PC Open Date & Time   | <b>FADTC</b>  |
| PC Close Date & Time  | <b>[NOT SUBMITTED]</b>  |
| PC Time stamp   | <b>[NOT SUBMITTED]</b>  |

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Folder: Uniques

Form: Rash\_Day

Generated On: 30 Apr 2021 19:52:48

|  |                           |
|--|---------------------------|
| TIMEPOINT                                  |                           |
| Select one response below if you have RASH | No <input type="radio"/>  |
|  | Yes <input type="radio"/> |
| PC Open Date & Time                        |                           |
| PC Close Date & Time                       |                           |
| PC Time Stamp                              |                           |

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

Folder: Uniques

HODECOD = MAAE

Form: Medical Attention\_Day

Generated On: 30 Apr 2021 19:52:48

TIMEPOINT

FATPT

Did you receive any **MEDICAL ATTENTION** (doctor visit,  
**other**) for any illness or symptoms?

SUPPFA.QVAL when QNAM=MAAEFL

No ☐Yes ☐

PC Time stamp

HOSTDTC

HOENDTC

PC Open Date &amp; Time

[NOT SUBMITTED]

PC Close Date &amp; Time

[NOT SUBMITTED]

**FA = Findings About****FACAT = REACTOGENICITY**

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**FASCAT = ADMINISTRATION SITE**

Folder: Uniques

**FALNKGRP =  
1060/2060**

Form: Underarm Gland\_Day

Generated On: 30 Apr 2021 19:52:48

**TIMEPOINT****FATPT**Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.****FAOBJ**None ☐

Please select one response below

Does not interfere with activity ☐Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity ☐**FAORRES when FATESTCD = SEV**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]**

FACAT = SAFETY

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

Folder: Uniques

Form: Safety Follow Up Diary

Generated On: 30 Apr 2021 19:52:48

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? No ☐ Yes ☐

FAORRES =Y when FATESTCD=CHGHLTH

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? No ☐ Yes ☐

FAORRES =Y when FATESTCD=COVIDEXP

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately. ☐

SUPPFA.QVAL when QNAM= CLIN2

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

FAORRES =Y when FATESTCD=NEWSYMP

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately. ☐

SUPPFA.QVAL when QNAM= CLIN2J

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? No ☐ Yes ☐

FAORRES =Y when FATESTCD= HLTHPCT

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

**Folder: Uniques**

**FASCAT = SAFETY DIARY**

**Form: Safety Follow Up Diary**

**Generated On: 30 Apr 2021 19:52:48**

**FACAT = SAFETY**

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= CLIN4A** I confirm I have read this message and will call the study clinic immediately ☐

|                                 |              |                        |
|---------------------------------|--------------|------------------------|
| Date and time of submission     | <b>FADTC</b> |                        |
| Patient Cloud Open Date & Time  |              | <b>[NOT SUBMITTED]</b> |
| Patient Cloud Close Date & Time |              | <b>[NOT SUBMITTED]</b> |

**[NOT SUBMITTED]**

**v13.005 Publish Checks to Prod CRF Version 1725: Uniques**

**Folder: Uniques**

**Form: Safety Report Form**

**Generated On: 30 Apr 2021 19:52:48**

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