

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**

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

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Participant ID

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

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**Folder: Uniques**

**Form: Visit Date**

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Was this visit performed? Yes

No

Visit date (dd MMM yyyy)

**[NOT SUBMITTED]**

Was visit performed at the participant's home or at the clinic?

**SVCNTMOD**

Home

Clinic

**DM = Demographics**

**DS = Disposition**

**MH = Medical History**

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Folder: Uniques

**DSCAT = PROTOCOL MILESTONE**

Form: Randomization

**DSTERM = RANDOMIZED**

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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**  **>=18 and <65 years and not at risk**

**MHCAT = RISK FACTOR FOR COVID-19**  **>=18 and <65 years and at risk**

**>=65 years**

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

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)  Yes  No **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 > 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**

v13.005 Publish Checks to Prod CRF Version 1725: Uniques **DSCAT = PROTOCOL MILESTONE**

Folder: Uniques

**DSSCAT = OPEN LABEL**

Form: Unblinding

Generated On: 30 Apr 2021 19:52:48

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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Folder: Uniques

Form: Unscheduled Visit Assessment

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Visit Date SVSTDTC

**Please check all assessments that apply for this visit**

Physical Exam	<span style="border: 1px solid black; padding: 2px;">SVUPDES</span>
Vital Signs	<span style="border: 1px solid black; padding: 2px;">SVUPDES</span>
Immunogenicity Assessment	<span style="border: 1px solid black; padding: 2px;">SVUPDES</span>
Pregnancy Test	<span style="border: 1px solid black; padding: 2px;">SVUPDES</span>

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Folder: Uniques

Form: Demographics

Generated On: 30 Apr 2021 19:52:48

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

Yes

**SUPPDM.QVAL when QNAM = PREVSCR**

No

If Yes, previous participant number

**SUBJID**

**SUPPDM.QVAL when QNAM = SUBJID1**

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**Form: Inclusion/Exclusion Criteria Summary**

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Did the participant meet all eligibility criteria?

Yes

No

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**IE = Inclusion/Exclusion Criteria Not Met**

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Folder: Uniques

Form: Inclusion/Exclusion Criteria

Generated On: 30 Apr 2021 19:52:48

Select inclusion criteria not met and/or exclusion criteria met

Criterion Type	<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"/>
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		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

No

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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="radio"/> No <input type="radio"/>
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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Folder: Uniques

**VSCAT = VITAL SIGNS**

Form: Vital Signs

Generated On: 30 Apr 2021 19:52:48

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

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

Other

**VSLOC**

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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Folder: Uniques

**VSCAT = VITAL SIGNS**

Form: Vital Signs - Dosing

Generated On: 30 Apr 2021 19:52:48

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

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

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) C   
F   
**VSTEST = Temperature** **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** **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)

**VSCAT = VITAL SIGNS**

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

Folder: Uniques

Form: Vital Signs - Dosing

Generated On: 30 Apr 2021 19:52:48

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

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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Folder: Uniques

Form: Physical Examination

Generated On: 30 Apr 2021 19:52:48

Was the physical examination performed?

**FAOBJ**

**FAORRES when FATESTCD = OCCUR**

Yes

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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Folder: Uniques

Form: Childbearing Potential

Generated On: 30 Apr 2021 19:52:48

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

Is the participant of childbearing potential? **RPTSTCD=CHILDPOT** **RPORRES** Yes   
No

If No, what is the reason? Surgically sterile   
**SUPPRP.QVAL when QNAM=CBRSN** 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**

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Folder: Uniques

Form: Pregnancy Test

Generated On: 30 Apr 2021 19:52:48

**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 **LBDTC** \_\_\_\_\_

Collection time \_\_\_\_\_

**EC = Exposure as Collected**

**EX = Exposure**

**DS = Disposition**

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Folder: Uniques

Form: Exposure

Generated On: 30 Apr 2021 19:52:48

**ECPRESP = 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

**ECREASOC**

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

**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

**ISCAT = IMMUNOGENICITY ASSESSMENT**

Generated On: 30 Apr 2021 19:52:48

Was the sample collected?

Yes

**ISSTAT = NOT DONE** No

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

**ISDTC**

Fixed Unit: (24 HR)

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Folder: Uniques

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 30 Apr 2021 19:52:48

**MBCAT = SARS-CoV-2**

**MBTESTCD = SARSCOV2**

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

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

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

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

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

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

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

**MB = Microbiology Specimen**

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

**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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Folder: Uniques

Form: Safety Call

Generated On: 30 Apr 2021 19:52:48

**SVPRESP = Y**

Was Contact Attempted?

**SVOCCUR**

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**

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

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Did the participant experience any adverse events?

Yes

No

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

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**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

Generated On: 30 Apr 2021 19:52:48

**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** No

**SUPPFA.QVAL when QNAM = MAAEFL** **SUPPAE.QVAL when QNAM = MAAEFL** No

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? **AEENRF** Yes

No

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59) **AEENDTC** **FADTC** **CEENDTC** Fixed Unit: (24 HR)

Severity Grade 1/Mild

**FAORRES when FATESTCD = SEV** **CETOXGR** **AETOXGR** **AESEV** **CESEV** Grade 2/Moderate

Grade 3/Severe

Grade 4

Is the adverse event serious? **AESER** Yes

No

AE is serious due To (check all that apply)

Death **AESDTH**

Life threatening **AESLIFE**

Requires inpatient or prolongation of existing Hospitalization **AESHOSP**

Hospital Admission Date (dd MMM yyyy) **HODECOD = HOSPITAL** **HOSDTC**

Hospital Discharge Date (dd MMM yyyy) **SUPPAE.QVAL when QNAM = AEHOSPST/ AEHOSPEN** **HOENDTC**

Admitted to ICU? **HOTERM** Yes

**HOCCUR** No

**HODECOD = ICU** **HOCAT = ADVERSE EVENTS** Unknown

Number of Days in ICU **HODUR**

Persistent or significant disability or incapacity **AESDISAB**

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**Folder: Uniques**

**Form: Adverse Events**

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

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="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	<b>AERELNST</b>	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	<b>AEACN</b>	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	<b>AEACNOTH</b>	
None		
Concomitant Medication		
Concomitant Procedure		
Outcome	<b>AEOUT</b>	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
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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**Folder: Uniques**

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

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

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Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

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

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**CM = Concomitant and Prior Medications**

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Folder: Uniques

Form: Prior/Concomitant Medication and Vaccination

Generated On: 30 Apr 2021 19:52:48

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

Name of Medication  **CMTRT**

Prophylaxis  **SUPPCM.QVAL when QNAM = CMLPX** Yes   
No

Indication  **CMINDC**

Dose per administration  **CMDOSE**

Dose unit  mg   
ug   
mL   
g  **CMDOSU**  
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify  **SUPPCM.QVAL when QNAM = CMUOTHSP**

Frequency  once daily   
twice daily   
three times daily  **CMDOSFRQ**  
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  Oral   
Topical   
Subcutaneous  **CMROUTE**  
Transdermal   
Intraocular   
Intramuscular

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

Folder: Uniques

Form: Prior/Concomitant Medication and Vaccination

Generated On: 30 Apr 2021 19:52:48

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Respiratory (Inhalation)

Intralesional

Intraperitoneal

**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

---

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

**Folder: Uniques**

**Form: Concomitant Procedures Summary**

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

---

Were any concomitant procedures performed?

Yes

No

---

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

---

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

Folder: Uniques

**PRCAT = CONCOMITANT PROCEDURES**

Form: Concomitant Procedures

Generated On: 30 Apr 2021 19:52:48

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>	

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

Folder: Uniques

**DSCAT = DISPOSITION EVENT**

Form: Dosing Discontinuation

**DSSCAT = STUDY TREATMENT**

Generated On: 30 Apr 2021 19:52:48

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

- Primary reason for dosing discontinuation
- AE (specify)
  - SAE (specify)
  - Death
  - Lost To Follow-up
  - Physician decision (specify)
  - Pregnancy
  - Protocol deviation (specify)
  - Study Terminated By Sponsor
  - Withdrawal of consent by participant (specify)
  - Due to SARS-COV-2
  - Other

**DSTERM**

**DSDECOD**

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**

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

Folder: Uniques

**DSCAT = DISPOSITION EVENT**

Form: End of Study / Study Discontinuation

**DSSCAT = END OF STUDY**

Generated On: 30 Apr 2021 19:52:48

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) **DDDTC** **DTHDTC and DTHFL = Y**

Was autopsy performed? Yes

**DDTESTCD = AUTOPERF** **DDORRES** No

**DDTEST = Autopsy performed** Unknown

**[NOT SUBMITTED]**

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

**Folder: Uniques**

**Form: Continuing**

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

---

Is the participant continuing to the next visit?

Yes

No

---

**SC = Subject Characteristics**

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

Folder: Uniques

Form: Risk of Exposure

**SCCAT = COVID-19 EXPOSURE**

Generated On: 30 Apr 2021 19:52:48

**Occupational Risk** **SCSCAT**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) **SCORRES** Yes  No

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) **SCORRES** Yes  No

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) **SCORRES** Yes  No

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) **SCORRES** Yes  No

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) **SCORRES** Yes  No

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) **SCORRES** Yes  No

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) **SCORRES** Yes  No

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) **SCORRES** Yes  No

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) **SCORRES** Yes  No

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) **SCORRES** Yes  No

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) **SCORRES** Yes  No

**Other** **SCORRES** Yes  No

Specify **SCORRES** **SUPPSC.QVAL when QNAM = SCORRS1 / SCORRS2 when text > 200, split into multiple**

**Location and Living Circumstances Risk** (check all that apply) **SCSCAT**

**No Risk Identified** **SCORRES**

**Resides in Nursing Home or Assisted Living Facility** **SCORRES**

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) **SCORRES**

**SCTEST**

**SCTEST**

**SC = Subject Characteristics**

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

Folder: Uniques

Form: Risk of Exposure

Generated On: 30 Apr 2021 19:52:48

**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**

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

Folder: Uniques

Form: COVID-19 Contact

Generated On: 30 Apr 2021 19:52:48

---

Date of Contact	<b>SVSTDTC</b>	
Time of Contact		
Type of Contact	<b>SVCNTMOD = IN PERSON</b>	Clinic Visit - Scheduled <input type="checkbox"/>
		Clinical Visit - Unscheduled <input type="checkbox"/>
	<b>SVCNTMOD = TELEPHONE</b>	Safety Call <input type="checkbox"/>
		Convalescent Tele-visit <input type="checkbox"/>
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

Generated On: 30 Apr 2021 19:52:48

**CECAT = EFFICACY**

**CESCAT= COVID-19**

**CEPRESP = 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

Generated On: 30 Apr 2021 19:52:48

CECAT = EFFICACY  
CESCAT = COVID-19

CEPRES = Y

- Day 34
- Day 35
- Day 36
- Day 37
- Day 38
- Day 39
- Day 40

FATPT

CETPT

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

CEOCCUR = Y when Temp >= 38C VSORRES/VSORRESU F

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

**CE = Clinical Events**

**for Topline records**

**FA = Findings About**

**FACAT = EFFICACY**

**FASCAT= COVID-19**

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

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

Folder: Uniques

Form: Symptom Log

Generated On: 30 Apr 2021 19:52:48

**CECAT = EFFICACY**

**CESCAT= COVID-19**

**CEPRESP = Y**

	<b>FASTAT = NOT DONE</b>	Not Done	<input type="radio"/>	
Fatigue		None	<input type="radio"/>	<b>CEOCCUR= N</b>
<b>FAOBJ</b>	<b>CETERM</b>	Mild	<input type="radio"/>	
	<b>CESEV</b>	Moderate	<input type="radio"/>	<b>FAORRES</b>
		Severe	<input type="radio"/>	
	<b>CESTAT = NOT DONE</b>	Not Done	<input type="radio"/>	<b>FASTAT = NOT DONE</b>
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>	Moderate	<input type="radio"/>	<b>FAORRES</b>
		Severe	<input type="radio"/>	
	<b>CESTAT = NOT DONE</b>	Not Done	<input type="radio"/>	<b>FASTAT = NOT DONE</b>
Body Aches		None	<input type="radio"/>	<b>CEOCCUR= N</b>
<b>FAOBJ</b>	<b>CETERM</b>	Mild	<input type="radio"/>	
	<b>CESEV</b>	Moderate	<input type="radio"/>	<b>FAORRES</b>
		Severe	<input type="radio"/>	
	<b>CESTAT = NOT DONE</b>	Not Done	<input type="radio"/>	<b>FASTAT = NOT DONE</b>
Headache		None	<input type="radio"/>	<b>CEOCCUR= N</b>
<b>FAOBJ</b>	<b>CETERM</b>	Mild	<input type="radio"/>	
	<b>CESEV</b>	Moderate	<input type="radio"/>	<b>FAORRES</b>
		Severe	<input type="radio"/>	
	<b>CESTAT = NOT DONE</b>	Not Done	<input type="radio"/>	<b>FASTAT = NOT DONE</b>
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>	Moderate	<input type="radio"/>	<b>FAORRES</b>
		Severe	<input type="radio"/>	
	<b>CESTAT = NOT DONE</b>	Not Done	<input type="radio"/>	<b>FASTAT = NOT DONE</b>
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>	Moderate	<input type="radio"/>	<b>FAORRES</b>
		Severe	<input type="radio"/>	
	<b>CESTAT = NOT DONE</b>	Not Done	<input type="radio"/>	<b>FASTAT = NOT DONE</b>
Nasal Congestion		None	<input type="radio"/>	<b>CEOCCUR= N</b>
<b>CETERM</b>	<b>FAOBJ</b>			

v13.005 Publish Checks to Prod CRF

Version 1725 (1822)

39 of 70

**CE = Clinical Events**

**for Topline records**

**FA = Findings About**

**FACAT = EFFICACY**

**FASCAT= COVID-19**

**FATESTCD/FATEST = SEV/ Severity/Intesity**

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

Folder: Uniques

Form: Symptom Log

Generated On: 30 Apr 2021 19:52:48

**CECAT = EFFICACY**

**CESCAT= COVID-19**

**CEPRES = Y**

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

**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 **MBSPEC** Nasopharyngeal Swab   
Nasal Swab   
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   
Day 5   
Day 7  **MBTPT**  
Day 9   
Day 14   
Day 21   
Day 28

Was Saliva Collected? Yes   
No  **MBSTAT = NOT DONE**  
**MBREASND=COVID-19 NEGATIVE** **MBSTAT = NOT DONE** NA (COVID-19 Negative)

Date of Collection **MBDTC**

Visit Day 3   
Day 5   
Day 7   
Day 9  **MBTPT**  
Day 14   
Day 21   
Day 28

Was Saliva Collected? Yes   
No  **MBSTAT = NOT DONE**  
**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  **MBTPT**  
Day 21   
Day 28

Was Saliva Collected? Yes   
No  **MBSTAT = NOT DONE**  
**MBREASND=COVID-19 NEGATIVE** **MBSTAT = NOT DONE** NA (COVID-19 Negative)

**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 **MBDTC**

Visit

Day 3

Day 5

Day 7

**MBTPT** Day 9

Day 14

Day 21

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**

Visit

Day 3

Day 5

Day 7

Day 9

**MBTPT** Day 14

Day 21

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**

Visit

Day 3

Day 5

Day 7

Day 9

Day 14

**MBTPT** Day 21

Day 28

Was Saliva Collected? Yes

**MBSTAT = NOT DONE** 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

**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

**ISSTAT = NOT DONE**

No

**FAORRES**

**ISREASND = COVID-19 NEGATIVE**

**ISSTAT = NOT DONE**

NA (COVID-19 Negative)

Date of Collection

**ISDTC**

**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 SpO2  $\leq$  93% on room air at sea level?

**FAOBJ**

**CEOCCUR**

Yes   
No

**FAORRES**

**CETERM = Oxygen Saturation of SpO2  $\leq$  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 PaO2/FIO2 Ratio  $<$  300 mm Hg?

**FAOBJ**

**CEOCCUR**

Yes   
No

**FAORRES**

**CETERM = PaO2/FIO2 Ratio  $<$  300 mmHg**

If Yes, provide:

Start Date

**CESTDTC**

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

**VSDTC**

End Date

**CEDTC/ CEENDTC**

**FAENDTC**

PaO2

Fixed Unit: mmHg

**VSORRES when VSTESTCD = PaO2/FIO2**

**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**

v13.005 Publish Checks to Prod CRF

Version 1725 (1822)

46 of 70

**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 < 90 mmHg, Diastolic Blood Pressure < 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

47 of 70

Version 1725 (1822)

**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

**CEOCCUR**

No

Start Date **FADTC** **CEDTC/CESTDTC**

**FAOBJ**

Neurologic Dysfunction?

**CETERM = Neurologic Dysfunction**

**FAORRES**

Yes

**CEOCCUR**

No

Start Date **FADTC** **CEDTC/CESTDTC**

Evidence of Pneumonia:

Clinical Evidence **FAOBJ = Clinical Evidence of Pneumonia**

**CETERM = Clinical Evidence of Pneumonia**

**FAORRES**

Yes

**CEOCCUR**

No

Date of Assessment **FADTC** **CEDTC/CESTDTC**

Radiographical Evidence **FAOBJ = Radiographical Evidence of Pneumonia**

**CETERM = Radiographical Evidence of Pneumonia**

**FAORRES**

Yes

**CEOCCUR**

No

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**

---

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"/>
	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"/>

**VISIT**

**Case Report Form**

Visit Date	_____
Demographics	_____
Enrollment	_____
Inclusion/Exclusion Criteria Summary	_____
Inclusion/Exclusion Criteria	_____
Medical History Summary	_____
Medical History	<b>SVUPDES 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> <b>Concatenate all selected values</b>
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.

**CELNKGRP = 1150/2150**

Was **TEMPERATURE** taken? **VSSTAT = NOT DONE**  
*Missing records will also be considered as NOT DONE* Yes  No

**VSLNKGRP = 1150/2150**

Please record your **TEMPERATURE** in °F Fixed Unit: °F  
**VSTEST = Temperature** **VSORRES / VSORRESU when VSTESTCD = TEMP**

**CETERM = Fever**

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**

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

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

**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

**CEPRESP = 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

**CELNKGRP = 1030/2030**

**FAORRES when FATESTCD = SEV**

Repeated use of over-the-counter pain reliever > 24 hours or

**FALNKGRP = 1030/2030**

**CEOCCUR = Y**

interferes with activity

Any use of prescription pain reliever or prevents daily activity

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

**FAOBJ = Erythema**

**CEOCCUR**

es

**CETERM = Erythema**

**FAORRES when FATESTCD = OCCUR**

No

**CELNKGRP = 1040/2040**

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

**FAORRESU**

**FALNKGRP = 1040/2040**

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

**FAORRES when FATESTCD = LDIAM**

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

**FAOBJ**

**CEOCCUR**

Yes

**CELNKGRP = 1050/2050**

**CETERM**

**FAORRES when FATESTCD = OCCUR**

No

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

**FAORRESU**

**FALNKGRP = 1050/2050**

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

**CELNKGRP = 1060/2060**

**CEOCCUR = Y**

Repeated use of over-the-counter pain reliever > 24 hours or

interferes with some activity

**FALNKGRP = 1060/2060**

**FAORRES when FATESTCD = SEV**

Any use of prescription pain reliever or prevents daily activity

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

**CECAT = REACTOGENICITY**

**FACAT = REACTOGENICITY**

**CESCAT = SYSTEMIC**

**FASCAT = SYSTEMIC**

v13.005 Publish Checks to Prod CRF Vers

Folder: Uniques

Form: General\_Day

Generated On: 30 Apr 2021 19:52:48

**CEPRESP = Y**

TIMEPOINT

**FATPT**

**CELNKGRP = 1070/2070**

HEADACHE

**FAOBJ**

**CEOCCUR = N**

None

**CETERM**

No interference with activity

**FALNKGRP = 1070/2070**

Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity

**FAORRES when FATESTCD = SEV**

**CEOCCUR = Y**

Any use of prescription pain reliever or prevents daily activity

FATIGUE

**CELNKGRP = 1080/2080**

**CETERM**

**FAOBJ**

**CEOCCUR = Y**

None

No interference with activity

**FALNKGRP = 1080/2080**

**FAORRES when FATESTCD = SEV**

Some interference with activity

Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

**CELNKGRP = 1090/2090**

**CETERM = Myalgia**

**FAOBJ = Myalgia**

**CEOCCUR = Y**

None

No interference with activity

**FALNKGRP = 1090/2090**

**FAORRES when FATESTCD = SEV**

Some interference with activity

Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

**CELNKGRP = 1100/2100**

**FAOBJ = Arthralgia**

**CETERM = Arthralgia**

**CEOCCUR = Y**

None

No interference with activity

**FALNKGRP = 1100/2100**

**FAORRES when FATESTCD = SEV**

Some interference with activity

Significant; prevents daily activity

NAUSEA/VOMITING

**CELNKGRP = 1110/2110**

**CETERM**

**FAOBJ**

**CEOCCUR = N**

None

No interference with activity or 1-2 episodes/24 hours

**FALNKGRP = 1110/2110**

**FAORRES when FATESTCD = SEV**

**CEOCCUR = Y**

Some interference with activity or >2 episodes/24 hours

Prevents daily activity, requires outpatient IV hydration

CHILLS

**CELNKGRP = 1120/2120**

**CETERM**

**FAOBJ**

**CEOCCUR = Y**

**CEOCCUR = N**

None

No interference with activity

**FALNKGRP = 1120/2120**

**FAORRES when FATESTCD = SEV**

Some interference with activity not requiring medical attention

Prevents daily activity and requires medical attention

**HOTERM = MEDICALLY ATTENDED**

**HODECOD = MAAE**

**HOPRESP = Y**

Did you receive any **MEDICAL ATTENTION** (doctor visit,

**HOCCUR=N**

No

other) for any illness or symptoms?

**SUPPFA.QVAL when QNAM=MAAEFL**

v13.005 Publish Checks to Prod CRF

**SUPPCE.QVAL when QNAM=MAAEFL**

54 of 70

Version 1725 (1822)

**HO = Healthcare Encounters**

**FA = Findings About**

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

**FACAT = REACTOGENICITY**

Folder: Uniques

**FASCAT = SYSTEMIC**

Form: General\_Day

Generated On: 30 Apr 2021 19:52:48

**HOCAT = EDIARY**

**HOCCUR = Y** Yes

PC Time stamp	<b>HOSTDTC</b>	<b>HOENDTC</b>	<b>FADTC</b>	
PC Open Date & Time				<b>[NOT SUBMITTED]</b>
PC Close Date & Time				<b>[NOT SUBMITTED]</b>

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

Does not interfere with activity

Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity

**FAORRES when FATESTCD = SEV**

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]**

**FA = Findings About**

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

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   
No   
**FAOBJ**

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 & Time **[NOT SUBMITTED]**

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

**FA = Findings About**

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

**HEADACHE**

**FAOBJ**

**FAORRES when FATESTCD = SEV**

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp **FADTC**

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

PC Close Date & 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 & 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: 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** No interference with activity

**FAOBJ = Arthralgia** Some interference with activity

**FAORRES when FATESTCD = SEV** Significant; prevents daily

activity

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

None

**NAUSEA/VOMITING**

No interference with activity or  
1-2 episodes/24 hours

**FAOBJ**

**FAORRES when FATESTCD = SEV**

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**

<b>TIMEPOINT</b>	<b>FATPT</b>	
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"/>
	<b>FAORRES when FATESTCD = SEV</b>	Some interference with activity not requiring medical attention <input type="radio"/>
		Prevents daily activity and requires medical attention <input type="radio"/>
PC Open Date & Time	<b>FADTC</b>	
PC Close Date & Time		<b>[NOT SUBMITTED]</b>
PC Time stamp		<b>[NOT SUBMITTED]</b>

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

**Folder: Uniques**

**Form: Rash\_Day**

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

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**TIMEPOINT**

---

Select one response below if you have **RASH**

No

Yes

---

PC Open Date & Time

---

PC Close Date & Time

---

PC Time Stamp

---

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

<b>TIMEPOINT</b>	<b>FATPT</b>
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="radio"/> Yes <input type="radio"/>
PC Time stamp	<b>HOSTDTC</b> <b>HOENDTC</b>
PC Open Date & Time	<b>[NOT SUBMITTED]</b>
PC Close Date & Time	<b>[NOT SUBMITTED]</b>

**FA = Findings About**

**FACAT = REACTOGENICITY**

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

**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):

**FAOBJ**

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

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 = FOLLOW UP**

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**

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**

**FA = Findings About**

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 **FADTC**

Patient Cloud Open Date & Time **[NOT SUBMITTED]**

Patient Cloud Close Date & Time **[NOT SUBMITTED]**

**[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"/> No <input type="checkbox"/>
Death	Yes <input type="checkbox"/> No <input type="checkbox"/>
Life threatening	Yes <input type="checkbox"/> No <input type="checkbox"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="checkbox"/> No <input type="checkbox"/>
Persistent or significant disability or incapacity	Yes <input type="checkbox"/> No <input type="checkbox"/>
Congenital anomaly or birth defect	Yes <input type="checkbox"/> No <input type="checkbox"/>
Other medically important event	Yes <input type="checkbox"/> 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>	
_____	