

### **16.1.2 Sample Case Report Form (Unique Pages Only)**

This section contains the following document:

[Sample case report form, version 10.002 dated 04 May 2021.](#)

PRODUCTION RELEASE (v10.002) - MASTER

Generated By: (b) (6)

Generated On: 04 May 2021 23:11:23

All time stamps listed in this document are displayed in GMT

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Demographics**

**Generated On: 04 May 2021 23:11:23**

Date of Birth (MMM yyyy)	
Age	
Age Units	
Age (Derived)	
Sex	Female <input type="checkbox"/> Male <input type="checkbox"/>
Ethnicity	Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Not Reported <input type="checkbox"/> Unknown <input type="checkbox"/>
Race (Check All That Apply)	
White	
Black	
Asian	
American Indian or Alaska Native	
Native Hawaiian or other Pacific Islander	
Other	
If race is Other, specify	
Unknown	
Not reported	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 04 May 2021 23:11:23**

Date of Informed Consent ( <i>dd MMM yyyy</i> )	
Month and Year of Informed Consent (derived)	
Year of Informed Consent (derived)	
Protocol Version	Original <input type="checkbox"/>
	Amendment 1 <input type="checkbox"/>
	Amendment 2 <input type="checkbox"/>
	Amendment 3 <input type="checkbox"/>
	Amendment 4 <input type="checkbox"/>
	Amendment 5 <input type="checkbox"/>
Was participant enrolled in the study?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="checkbox"/>
	Inclusion/Exclusion <input type="checkbox"/>
	Cohort Full <input type="checkbox"/>
	Other <input type="checkbox"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If Yes, previous participant number	
Enrollment Trigger	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Amendment 5 Enrollment**

**Generated On: 04 May 2021 23:11:23**

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mRNA-1273-P301 Participant ID

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Dose Level Assigned

mRNA-1273.351 20ug ☐

mRNA-1273.351 50ug ☐

mRNA-1273 25ug + ☐

mRNA-1273.351 25ug ☐

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 04 May 2021 23:11:23**

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Did the participant meet all eligibility criteria?

Yes ☐

No ☐

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria**

**Generated On: 04 May 2021 23:11:23**

**Select inclusion criteria not met and/or exclusion criteria met**

Criterion Type	Inclusion <input type="checkbox"/>	Exclusion <input type="checkbox"/>
Criterion Identifier	1 <input type="checkbox"/>	
	2 <input type="checkbox"/>	
	3 <input type="checkbox"/>	
	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"/>	



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 04 May 2021 23:11:23**

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Were any significant conditions reported??

Yes ☐

No ☐

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Medical History**

**Generated On: 04 May 2021 23:11:23**

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

PRODUCTION RELEASE

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Central Laboratory**

**Generated On: 04 May 2021 23:11:23**

Collection date (dd MMM yyyy)

Lab panel Hematology ☒

Chemistry ☐

Serology ☐

Coagulation ☐

Was the sample collected? Yes ☐

No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐

Chemistry ☒

Serology ☐

Coagulation ☐

Was the sample collected? Yes ☐

No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐

Chemistry ☐

Serology ☐

Coagulation ☒

Was the sample collected? Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Central Laboratory with Serology**

**Generated On: 04 May 2021 23:11:23**

Collection date (dd MMM yyyy)

Lab panel Hematology ☒  
Chemistry ☐  
Serology ☐  
Coagulation ☐

Was the sample collected? Yes ☐  
No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐  
Chemistry ☒  
Serology ☐  
Coagulation ☐

Was the sample collected? Yes ☐  
No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐  
Chemistry ☐  
Serology ☒  
Coagulation ☐

Was the sample collected? Yes ☐  
No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐  
Chemistry ☐  
Serology ☐

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Central Laboratory with Serology**

**Generated On: 04 May 2021 23:11:23**

		Coagulation	<input checked="" type="radio"/>
Was the sample collected?		Yes	<input type="radio"/>
		No	<input type="radio"/>
Collection time (00:00-23:59)	Fixed Unit: (24 HR)		
Collection date and time (derived)			

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Central Laboratory with FSH/Serology**

**Generated On: 04 May 2021 23:11:23**

Collection date (dd MMM yyyy)

Lab panel

Hematology ☒

Chemistry ☐

Serology ☐

Coagulation ☐

FSH ☐

Was the sample collected?

Yes ☐

No ☐

Collection time (00:00-23:59)

Fixed Unit: (24 HR)

Collection date and time (derived)

Lab panel

Hematology ☐

Chemistry ☒

Serology ☐

Coagulation ☐

FSH ☐

Was the sample collected?

Yes ☐

No ☐

Collection time (00:00-23:59)

Fixed Unit: (24 HR)

Collection date and time (derived)

Lab panel

Hematology ☐

Chemistry ☐

Serology ☒

Coagulation ☐

FSH ☐

Was the sample collected?

Yes ☐

No ☐

Collection time (00:00-23:59)

Fixed Unit: (24 HR)

Collection date and time (derived)

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(v10.002) (1868)

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Central Laboratory with FSH/Serology**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Hematology <input type="checkbox"/>
	Chemistry <input type="checkbox"/>
	Serology <input type="checkbox"/>
	Coagulation <input checked="" type="checkbox"/>
	FSH <input type="checkbox"/>
Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection time (00:00-23:59)	Fixed Unit: (24 HR)

Collection date and time (derived)

Lab panel	Hematology <input type="checkbox"/>
	Chemistry <input type="checkbox"/>
	Serology <input type="checkbox"/>
	Coagulation <input type="checkbox"/>
	FSH <input checked="" type="checkbox"/>
Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection time (00:00-23:59)	Fixed Unit: (24 HR)

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 04 May 2021 23:11:23**

Date of assessment ( <i>dd MMM yyyy</i> )		
Is the participant of childbearing potential?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If No, what is the reason?	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		
If Surgically sterile, date of surgery ( <i>dd MMM yyyy</i> )		
Date of surgery unknown		
If Post-menopausal, date of last menstruation ( <i>dd MMM yyyy</i> )		
Date of last menstruation unknown		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 04 May 2021 23:11:23**

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test ( <i>dd MMM yyyy</i> )	
<hr/>	
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
<hr/>	
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Screening**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Height cm   
in

Weight kg   
lb

BMI (*xxx.x*) Fixed Unit: kg/m<sup>2</sup>

BMI units

Timepoint Pre-Dose ☒  
Post-Dose ☐

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Vital Signs Date and Time (derived)

Temperature (*xxx.x*) C   
F

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify

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

Pulse units

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

Respiratory Rate units

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

Systolic Blood Pressure units

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Diastolic Blood Pressure units	
<hr/>	
Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
<hr/>	
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
<hr/>	
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)
<hr/>	
Vital Signs Date and Time (derived)	
<hr/>	
Temperature ( <i>xxx.x</i> )	C <input type="radio"/>
	F <input type="radio"/>
<hr/>	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
<hr/>	
If Other, specify	
Pulse ( <i>xxx</i> )	Fixed Unit: beats/min
<hr/>	
Pulse units	
<hr/>	
Respiratory Rate ( <i>xxx</i> )	Fixed Unit: breaths/min
<hr/>	
Respiratory Rate units	
<hr/>	
Systolic Blood Pressure ( <i>xxx</i> )	Fixed Unit: mmHg
<hr/>	
Systolic Blood Pressure units	
<hr/>	
Diastolic Blood Pressure ( <i>xxx</i> )	Fixed Unit: mmHg
<hr/>	
Diastolic Blood Pressure units	
<hr/>	



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 04 May 2021 23:11:23**

Collection date (*dd MMM yyyy*)

Lab Test

Nasopharyngeal Swab 1 ☒

Nasopharyngeal Swab 2 ☐

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

Lab Test

Nasopharyngeal Swab 1 ☐

Nasopharyngeal Swab 2 ☒

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 04 May 2021 23:11:23**

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test ( <i>dd MMM yyyy</i> )	
<hr/>	
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
<hr/>	
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 04 May 2021 23:11:23**

What was the date of randomization? ( <i>dd MMM yyyy</i> )	
What was the participant's randomization number?	
In what Cohort was the participant enrolled?	Cohort 1: Age $\geq$ 18 to $<$ 55 mRNA-1273 or Placebo <input type="radio"/>
	Cohort 2: Age $\geq$ 55 mRNA-1273 or Placebo <input type="radio"/>
Was this a Sentinel participant?	Yes <input type="radio"/>
	No <input type="radio"/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 04 May 2021 23:11:23**

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the study treatment? (Unblinded)	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	Fixed Unit: (24 HR) _____
<hr/>	
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Temp**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any rash or underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐  
No ☐

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

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Inj Site**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

PRODUCTION RELEASE (v10.002): MASTER

Folder: Diary Dose 1

Form: General

Generated On: 04 May 2021 23:11:23

TIMEPOINT

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

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

RASH

No ☐

PRODUCTION RELEASE  
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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: General**

**Generated On: 04 May 2021 23:11:23**

	Yes <input type="checkbox"/>
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Inj Pain**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Redness**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

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

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Swelling**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

PC Time stamp

PC Open Date & Time

PC Close Date & Time



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Headache**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Fatigue**

**Generated On: 04 May 2021 23:11:23**

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---

**TIMEPOINT**

---

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

---

---

PC Open Date & Time

---

---

PC Close Date & Time

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: MuscleAche**

**Generated On: 04 May 2021 23:11:23**

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---

**TIMEPOINT**

---

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

---

PC Open Date & Time

---

PC Close Date & Time

---

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: JointsAche**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your **JOINT**

**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Nausea**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the level of your

**NAUSEA/VOMITING**

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Chills**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

None ☐

No interference with activity ☐

Some interference with activity not requiring medical attention ☐

Prevents daily activity and requires medical attention ☐

PC Open Date & Time \_\_\_\_\_

PC Close Date & Time \_\_\_\_\_

PC Time stamp \_\_\_\_\_

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Rash**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Open Date & Time

PC Close Date & Time

PC Time Stamp

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: MedAtten**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: UnderarmGland**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

PC Close Date and Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Safety Follow Up Diary**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

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

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

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

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

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 ☐

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1**

**Form: Safety Follow Up Diary**

**Generated On: 04 May 2021 23:11:23**

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

Date and time of submission	_____
Patient Cloud Open Date & Time	_____
Patient Cloud Close Date & Time	_____

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 2 Day 8**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 2 Day 8**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 2 Day 8**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 2 Day 8**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 2 Day 8**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 2 Day 8**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 3 Day 15**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Height cm   
in

Weight kg   
lb

BMI (xxx.x) Fixed Unit: kg/m<sup>2</sup>

BMI units

Timepoint Pre-Dose ☒  
Post-Dose ☐

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (dd MMM yyyy)

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

Vital Signs Date and Time (derived)

Temperature (xxx.x) C   
F

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify

Pulse (xxx) Fixed Unit: beats/min

Pulse units

Respiratory Rate (xxx) Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Diastolic Blood Pressure units	
<hr/>	
Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
<hr/>	
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
<hr/>	
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)
<hr/>	
Vital Signs Date and Time (derived)	
<hr/>	
Temperature ( <i>xxx.x</i> )	C <input type="radio"/>
	F <input type="radio"/>
<hr/>	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
<hr/>	
If Other, specify	
Pulse ( <i>xxx</i> )	Fixed Unit: beats/min
<hr/>	
Pulse units	
<hr/>	
Respiratory Rate ( <i>xxx</i> )	Fixed Unit: breaths/min
<hr/>	
Respiratory Rate units	
<hr/>	
Systolic Blood Pressure ( <i>xxx</i> )	Fixed Unit: mmHg
<hr/>	
Systolic Blood Pressure units	
<hr/>	
Diastolic Blood Pressure ( <i>xxx</i> )	Fixed Unit: mmHg
<hr/>	
Diastolic Blood Pressure units	
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 04 May 2021 23:11:23**

Collection date (*dd MMM yyyy*)

Lab Test

Nasopharyngeal Swab 1 ☒

Nasopharyngeal Swab 2 ☐

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

Lab Test

Nasopharyngeal Swab 1 ☐

Nasopharyngeal Swab 2 ☒

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Pregnancy Test**

**Generated On: 04 May 2021 23:11:23**

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test ( <i>dd MMM yyyy</i> )	
<hr/>	
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
<hr/>	
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Exposure**

**Generated On: 04 May 2021 23:11:23**

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the study treatment? (Unblinded)	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	Fixed Unit: (24 HR) _____
<hr/>	
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 4 Day 29**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Temp**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any rash or underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐  
No ☐

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

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Inj Site**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

PRODUCTION RELEASE (v10.002): MASTER

Folder: Diary Dose 2

Form: General

Generated On: 04 May 2021 23:11:23

TIMEPOINT

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

RASH

No ☐

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: General**

**Generated On: 04 May 2021 23:11:23**

	Yes <input type="checkbox"/>
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Inj Pain**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Redness**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

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

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Swelling**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Headache**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Fatigue**

**Generated On: 04 May 2021 23:11:23**

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**TIMEPOINT**

---

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time Stamp

---

---

PC Open Date & Time

---

---

PC Close Date & Time

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: MuscleAche**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: JointsAche**

**Generated On: 04 May 2021 23:11:23**

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---

**TIMEPOINT**

---

Select one response below to indicate the intensity of your **JOINT**

**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

---

PC Open Date & Time

---

PC Close Date & Time

---

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Nausea**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the level of your

**NAUSEA/VOMITING**

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Chills**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

None ☐

No interference with activity ☐

Some interference with activity not requiring medical attention ☐

Prevents daily activity and requires medical attention ☐

PC Open Date & Time \_\_\_\_\_

PC Close Date & Time \_\_\_\_\_

PC Time stamp \_\_\_\_\_

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Rash**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Open Date & Time

PC Close Date & Time

PC Time Stamp

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: MedAtten**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: UnderarmGland**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

PC Close Date and Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Safety Follow Up Diary**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

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

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

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

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

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 ☐

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2**

**Form: Safety Follow Up Diary**

**Generated On: 04 May 2021 23:11:23**

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

Date and time of submission \_\_\_\_\_

Patient Cloud Open Date & Time \_\_\_\_\_

Patient Cloud Close Date & Time \_\_\_\_\_

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 5 Day 36**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Visit date (dd MMM yyyy)	_____
--------------------------	-------

Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

*Only record new symptoms since the last visit*

Folder OID	_____
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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 5 Day 36**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

PRODUCTION RELEASE

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 5 Day 36**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 5 Day 36**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

Has the participant had close contact with a person known to have  
SARS-CoV-2 infection or COVID-19?

Yes ☐  
No ☐

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 5 Day 36**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 5 Day 36**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 6 Day 43**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 04 May 2021 23:11:23**

Collection date (*dd MMM yyyy*)

Lab Test

Nasopharyngeal Swab 1 ☒

Nasopharyngeal Swab 2 ☐

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

Lab Test

Nasopharyngeal Swab 1 ☐

Nasopharyngeal Swab 2 ☒

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 7 Day 57**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 85**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 85**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 85**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 85**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 113**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 113**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 113**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 113**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 141**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact Contact Made ☐  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐  
No ☐

Is participant COVID-19 symptomatic? Yes ☐  
No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 141**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 141**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 141**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 169**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 169**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 169**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 169**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 197**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 197**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

Has the participant had close contact with a person known to have SARS-CoV-2 infection or COVID-19?

Yes ☐

No ☐

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 197**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 197**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 8 Day 209**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 8 Day 209**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 8 Day 209**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 8 Day 209**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 8 Day 209**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 8 Day 209**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 237**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 237**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 237**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 237**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 265**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 265**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

Has the participant had close contact with a person known to have SARS-CoV-2 infection or COVID-19?

Yes ☐

No ☐

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 265**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 265**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 293**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 293**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 293**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 293**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 321**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 321**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 321**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 321**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 349**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 349**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

Has the participant had close contact with a person known to have SARS-CoV-2 infection or COVID-19?

Yes ☐  
No ☐

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 349**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 349**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 377**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 377**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 377**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call Day 377**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 9 Day 394**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 9 Day 394**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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(v10.002) (1868)

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 9 Day 394**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 9 Day 394**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 9 Day 394**

**Form: SARS-CoV-2 or COVID-19 Exposure Assessment**

**Generated On: 04 May 2021 23:11:23**

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

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

Social setting	
Family member	
Health Care Facility	
Work	
Travel	
Other	
Other, specify	
Estimated start date of exposure	
Estimated length of exposure (in days)	Fixed Unit: days
Estimated length of exposure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Visit 9 Day 394**

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

**Generated On: 04 May 2021 23:11:23**

Does the participant have symptoms of potential COVID-19?

Yes ☐

No ☐

Estimated date of first symptoms

*(If Yes, check all symptoms that apply)*

*Only record new symptoms since the last visit*

Cough	
Shortness of Breath	
Fever	
Sore Throat	
Chest Tightness/Pressure	
Headache	
Lethargy	
Myalgia	
Anosmia	
Dysgeusia	
Chills	
Repeated Shaking with chills	

**Please enter any other symptoms, one per line, in the log section below**

If Other, Specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Solicited Rash**

**Form: Solicited Rash**

**Generated On: 04 May 2021 23:11:23**

Vaccination Dose	Dose 1 <input type="checkbox"/>
	Dose 2 <input type="checkbox"/>
Days Relative to Vaccination	Day of vaccination <input type="checkbox"/>
	1 day from vaccination <input type="checkbox"/>
	2 days from vaccination <input type="checkbox"/>
	3 days from vaccination <input type="checkbox"/>
	4 days from vaccination <input type="checkbox"/>
	5 days from vaccination <input type="checkbox"/>
	6 days from vaccination <input type="checkbox"/>
Was rash evaluated by a healthcare provider?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If Yes, Investigator Site or Other Institution	
Investigator Site	_____
Other Institution	_____
Date of rash assessment by site investigator ( <i>dd MMM yyyy</i> )	_____
Rash Location	_____
What is the site investigator's assessment of the rash?	Grade 0 = No rash <input type="checkbox"/>
	Grade 1 = Localized rash, without associated symptoms <input type="checkbox"/>
	Grade 2 = maculopapular rash covering <50% body surface area <input type="checkbox"/>
	Grade 3 = urticarial rash covering > 50% body surface area <input type="checkbox"/>
	Grade 4 = Generalized exfoliative, ulcerative or bullous dermatitis, e.g. Stevens-Johnson syndrome or erythema multiforme <input type="checkbox"/>
Additional relevant information	_____

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Lymphadenopathy**

**Form: Lymphadenopathy**

**Generated On: 04 May 2021 23:11:23**

Vaccination Dose	Dose 1 <input type="checkbox"/>
	Dose 2 <input type="checkbox"/>
Days Relative to Vaccination	Day of vaccination <input type="checkbox"/>
	1 day from vaccination <input type="checkbox"/>
	2 days from vaccination <input type="checkbox"/>
	3 days from vaccination <input type="checkbox"/>
	4 days from vaccination <input type="checkbox"/>
	5 days from vaccination <input type="checkbox"/>
	6 days from vaccination <input type="checkbox"/>
Was lymphadenopathy evaluated by a healthcare provider?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If Yes, Investigator Site or Other Institution	
Investigator Site	<input type="text"/>
Other Institution	<input type="text"/>
Date of lymphadenopathy assessment	
by	
site investigator ( <i>dd MMM yyyy</i> ) <input type="text"/>	
Lymphadenopathy confirmed on physical exam?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Additional relevant information <input type="text"/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 04 May 2021 23:11:23**

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Did the participant meet all eligibility criteria?

Yes ☐

No ☐

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Inclusion/Exclusion Criteria**

**Generated On: 04 May 2021 23:11:23**

**Select inclusion criteria not met and/or exclusion criteria met**

Criterion Type	Inclusion <input type="checkbox"/>	Exclusion <input type="checkbox"/>
Criterion Identifier	1 <input type="checkbox"/>	
	2 <input type="checkbox"/>	
	3 <input type="checkbox"/>	
	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"/>	



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Unblinding**

**Generated On: 04 May 2021 23:11:23**

Did the participant consent to Part B?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Date of updated informed consent ( <i>dd MMM yyyy</i> ) _____	
Was the participant unblinded?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Date of unblinding ( <i>dd MMM yyyy</i> ) _____	
Treatment given in Part A	Placebo <input type="checkbox"/>
	mRNA-1273 50ug <input type="checkbox"/>
	mRNA-1273 100ug <input type="checkbox"/>
Will participant receive mRNA-1273?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
No Dose Flag	_____
Single Dose Flag	_____
Double Dose Flag	_____
Continuing with mRNA-1273	_____
OL-D1 Dose Post Matrix Merge Flag	_____
OL-D29 Dose Post Matrix Merge Flag	_____
OL-D57 Flag	_____
Safety Call OL-D85 Flag	_____

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Height cm   
in

Weight kg   
lb

BMI (*xxx.x*) Fixed Unit: kg/m<sup>2</sup>

BMI units

Timepoint Pre-Dose ☒  
Post-Dose ☐

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Vital Signs Date and Time (derived)

Temperature (*xxx.x*) C   
F

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify

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

Pulse units

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

Respiratory Rate units

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

Systolic Blood Pressure units

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Diastolic Blood Pressure units	
<hr/>	
Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	
<hr/>	
Time of assessment (00:00-23:59)	Fixed Unit: (24 HR)
<hr/>	
Vital Signs Date and Time (derived)	
<hr/>	
Temperature (xxx.x)	C <input type="radio"/>
	F <input type="radio"/>
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
<hr/>	
Pulse (xxx)	Fixed Unit: beats/min
<hr/>	
Pulse units	
<hr/>	
Respiratory Rate (xxx)	Fixed Unit: breaths/min
<hr/>	
Respiratory Rate units	
<hr/>	
Systolic Blood Pressure (xxx)	Fixed Unit: mmHg
<hr/>	
Systolic Blood Pressure units	
<hr/>	
Diastolic Blood Pressure (xxx)	Fixed Unit: mmHg
<hr/>	
Diastolic Blood Pressure units	
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 04 May 2021 23:11:23**

Collection date (*dd MMM yyyy*)

Lab Test

Nasopharyngeal Swab 1 ☒

Nasopharyngeal Swab 2 ☐

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

Lab Test

Nasopharyngeal Swab 1 ☐

Nasopharyngeal Swab 2 ☒

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Pregnancy Test**

**Generated On: 04 May 2021 23:11:23**

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test ( <i>dd MMM yyyy</i> )	
<hr/>	
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
<hr/>	
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Exposure**

**Generated On: 04 May 2021 23:11:23**

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the study treatment? (Unblinded)	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	Fixed Unit: (24 HR) _____
<hr/>	
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Central Laboratory - Serology**

**Generated On: 04 May 2021 23:11:23**

Was the sample collected? Yes ☐  
No ☐

Collection date (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Participant Decision Visit / OL-D1**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Temp**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any rash or underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐  
No ☐

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

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Inj Site**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

PRODUCTION RELEASE (v10.002): MASTER

Folder: Diary Dose 1 OL

Form: General

Generated On: 04 May 2021 23:11:23

TIMEPOINT

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

RASH

No ☐

PRODUCTION RELEASE  
(v10.002) (1868)

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: General**

**Generated On: 04 May 2021 23:11:23**

	Yes <input type="checkbox"/>
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Inj Pain**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Redness**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

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

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Swelling**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Headache**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Fatigue**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: MuscleAche**

**Generated On: 04 May 2021 23:11:23**

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**TIMEPOINT**

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Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

---

---

PC Open Date & Time

---

---

PC Close Date & Time

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: JointsAche**

**Generated On: 04 May 2021 23:11:23**

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**TIMEPOINT**

---

Select one response below to indicate the intensity of your **JOINT**

**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

---

PC Open Date & Time

---

PC Close Date & Time

---

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Nausea**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the level of your

**NAUSEA/VOMITING**

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Chills**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

None ☐

No interference with activity ☐

Some interference with activity not requiring medical attention ☐

Prevents daily activity and requires medical attention ☐

PC Open Date & Time \_\_\_\_\_

PC Close Date & Time \_\_\_\_\_

PC Time stamp \_\_\_\_\_



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: Rash**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Open Date & Time

PC Close Date & Time

PC Time Stamp

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: MedAtten**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 1 OL**

**Form: UnderarmGland**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

PC Close Date and Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D8**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Visit date (dd MMM yyyy)	_____
--------------------------	-------

Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

*Only record new symptoms since the last visit*

Folder OID	_____
------------	-------

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D8**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D8**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D15**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D15**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D15**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

PRODUCTION RELEASE

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Height cm   
in

Weight kg   
lb

BMI (*xxx.x*) Fixed Unit: kg/m<sup>2</sup>

BMI units

Timepoint Pre-Dose ☒  
Post-Dose ☐

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Vital Signs Date and Time (derived)

Temperature (*xxx.x*) C   
F

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify

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

Pulse units

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

Respiratory Rate units

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

Systolic Blood Pressure units

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Diastolic Blood Pressure units	
Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	Fixed Unit: (24 HR)
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	C <input type="radio"/>
	F <input type="radio"/>
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	Fixed Unit: beats/min
Pulse units	
Respiratory Rate (xxx)	Fixed Unit: breaths/min
Respiratory Rate units	
Systolic Blood Pressure (xxx)	Fixed Unit: mmHg
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	Fixed Unit: mmHg
Diastolic Blood Pressure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 04 May 2021 23:11:23**

Collection date (*dd MMM yyyy*)

Lab Test

Nasopharyngeal Swab 1 ☒

Nasopharyngeal Swab 2 ☐

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

Lab Test

Nasopharyngeal Swab 1 ☐

Nasopharyngeal Swab 2 ☒

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Pregnancy Test**

**Generated On: 04 May 2021 23:11:23**

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test ( <i>dd MMM yyyy</i> )	
<hr/>	
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
<hr/>	
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
<hr/>	



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Exposure**

**Generated On: 04 May 2021 23:11:23**

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the study treatment? (Unblinded)	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	Fixed Unit: (24 HR) _____
<hr/>	
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
<hr/>	
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D29**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Temp**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any rash or underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☐  
No ☐

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

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Inj Site**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

PRODUCTION RELEASE (v10.002): MASTER

Folder: Diary Dose 2 OL

Form: General

Generated On: 04 May 2021 23:11:23

TIMEPOINT

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

RASH

No ☐

PRODUCTION RELEASE  
(v10.002) (1868)

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: General**

**Generated On: 04 May 2021 23:11:23**

	Yes <input type="checkbox"/>
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	
PC Close Date & Time	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Inj Pain**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Redness**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

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

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Swelling**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

Yes ☐

No ☐

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

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Headache**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Fatigue**

**Generated On: 04 May 2021 23:11:23**

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**TIMEPOINT**

---

Select one response below to indicate the intensity of your

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

---

PC Open Date & Time

---

PC Close Date & Time

---

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: MuscleAche**

**Generated On: 04 May 2021 23:11:23**

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---

**TIMEPOINT**

---

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

---

---

PC Open Date & Time

---

---

PC Close Date & Time

---

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: JointsAche**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the intensity of your **JOINT**

**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Nausea**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Select one response below to indicate the level of your

**NAUSEA/VOMITING**

None ☐

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

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Chills**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

PC Open Date & Time

PC Close Date & Time

PC Time stamp



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: Rash**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Open Date & Time

PC Close Date & Time

PC Time Stamp

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: MedAtten**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

PC Close Date & Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Diary Dose 2 OL**

**Form: UnderarmGland**

**Generated On: 04 May 2021 23:11:23**

**TIMEPOINT**

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

PC Close Date and Time

Hidden Check (Programming Only)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D36**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D36**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Visit date (dd MMM yyyy)	_____
--------------------------	-------

Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

*Only record new symptoms since the last visit*

Folder OID	_____
------------	-------

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Height cm   
in

Weight kg   
lb

BMI (*xxx.x*) Fixed Unit: kg/m<sup>2</sup>

BMI units

Timepoint Pre-Dose ☒  
Post-Dose ☐

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Vital Signs Date and Time (derived)

Temperature (*xxx.x*) C   
F

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify

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

Pulse units

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

Respiratory Rate units

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

Systolic Blood Pressure units

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



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Vital Signs - Dosing**

**Generated On: 04 May 2021 23:11:23**

Diastolic Blood Pressure units	
Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	Fixed Unit: (24 HR)
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	C <input type="radio"/>
	F <input type="radio"/>
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	Fixed Unit: beats/min
Pulse units	
Respiratory Rate (xxx)	Fixed Unit: breaths/min
Respiratory Rate units	
Systolic Blood Pressure (xxx)	Fixed Unit: mmHg
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	Fixed Unit: mmHg
Diastolic Blood Pressure units	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 04 May 2021 23:11:23**

Collection date (dd MMM yyyy)

Lab Test

Nasopharyngeal Swab 1 ☒

Nasopharyngeal Swab 2 ☐

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

Collection time (00:00 - 23:59)

Collection date and time (derived)

Lab Test

Nasopharyngeal Swab 1 ☐

Nasopharyngeal Swab 2 ☒

Blood Collection for exposure to  
SARS-CoV-2 ☐

Was the sample collected?

Yes ☐

No ☐

Collection time (00:00 - 23:59)

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Exposure**

**Generated On: 04 May 2021 23:11:23**

Was study treatment given?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
If No, reason not given	Participant declined due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Physician withheld dose due to <input type="checkbox"/>
	Adverse Event <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-Up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated by Sponsor <input type="checkbox"/>
	Withdrawal of Consent by <input type="checkbox"/>
	Participant <input type="checkbox"/>
	Other <input type="checkbox"/>
<hr/>	
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____	
<hr/>	
What was the study treatment?	_____
What was the study treatment? (Unblinded)	_____
What was the treatment date? (dd MMM yyyy)	_____
What was the treatment time? (00:00-23:59)	Fixed Unit: (24 HR) _____
<hr/>	
Treatment Date and Time (derived)	_____
Which arm was used to give treatment?	Left Arm <input type="checkbox"/>
	Right Arm <input type="checkbox"/>
<hr/>	
What was the frequency of the study treatment dosing?	_____
What was the route of administration for the study treatment?	_____
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D57**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D64**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D64**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**PRODUCTION RELEASE (v10.002): MASTER****Folder: New Safety Follow Up Diary****Form: Safety Follow Up Diary****Generated On: 04 May 2021 23:11:23****TIMEPOINT**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

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

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

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

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

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 ☐

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 ☐

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: New Safety Follow Up Diary**

**Form: Safety Follow Up Diary**

**Generated On: 04 May 2021 23:11:23**

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

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

Date and time of submission

Patient Cloud Open Date & Time

Patient Cloud Close Date & Time

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D85**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D85**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D113**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D113**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D141**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D141**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D169**

**Form: Safety Call**

**Generated On: 04 May 2021 23:11:23**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

Has participant been exposed or potentially exposed to COVID-19? Yes ☐

No ☐

Is participant COVID-19 symptomatic? Yes ☐

No ☐

*Only record new symptoms since the last visit*

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Safety Call OL-D169**

**Form: Continuing**

**Generated On: 04 May 2021 23:11:23**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D181**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D181**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D181**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D181**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D209**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D209**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D209**

**Form: Physical Examination**

**Generated On: 04 May 2021 23:11:23**

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL-D209**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL Solicited Rash**

**Form: Solicited Rash**

**Generated On: 04 May 2021 23:11:23**

Vaccination Dose	Dose 1 <input type="checkbox"/>
	Dose 2 <input type="checkbox"/>
Days Relative to Vaccination	Day of vaccination <input type="checkbox"/>
	1 day from vaccination <input type="checkbox"/>
	2 days from vaccination <input type="checkbox"/>
	3 days from vaccination <input type="checkbox"/>
	4 days from vaccination <input type="checkbox"/>
	5 days from vaccination <input type="checkbox"/>
	6 days from vaccination <input type="checkbox"/>
Was rash evaluated by a healthcare provider?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If Yes, Investigator Site or Other Institution	
Investigator Site	<input type="text"/>
Other Institution	<input type="text"/>
Date of rash assessment by site investigator ( <i>dd MMM yyyy</i> )	<input type="text"/>
Rash Location	<input type="text"/>
What is the site investigator's assessment of the rash?	Grade 0 = No rash <input type="checkbox"/>
	Grade 1 = Localized rash, without associated symptoms <input type="checkbox"/>
	Grade 2 = maculopapular rash covering <50% body surface area <input type="checkbox"/>
	Grade 3 = urticarial rash covering > 50% body surface area <input type="checkbox"/>
	Grade 4 = Generalized exfoliative, ulcerative or bullous dermatitis, e.g. Stevens-Johnson syndrome or erythema multiforme <input type="checkbox"/>
Additional relevant information	<input type="text"/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL Lymphadenopathy**

**Form: Lymphadenopathy**

**Generated On: 04 May 2021 23:11:23**

Vaccination Dose	Dose 1 <input type="checkbox"/>
	Dose 2 <input type="checkbox"/>
Days Relative to Vaccination	Day of vaccination <input type="checkbox"/>
	1 day from vaccination <input type="checkbox"/>
	2 days from vaccination <input type="checkbox"/>
	3 days from vaccination <input type="checkbox"/>
	4 days from vaccination <input type="checkbox"/>
	5 days from vaccination <input type="checkbox"/>
	6 days from vaccination <input type="checkbox"/>
Was lymphadenopathy evaluated by a healthcare provider?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If Yes, Investigator Site or Other Institution	
Investigator Site	<input type="text"/>
Other Institution	<input type="text"/>
Date of lymphadenopathy assessment	
by	
site investigator ( <i>dd MMM yyyy</i> ) <input type="text"/>	
Lymphadenopathy confirmed on physical exam?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Additional relevant information <input type="text"/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: OL End of Treatment**

**Form: Dosing Discontinuation**

**Generated On: 04 May 2021 23:11:23**

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

Adverse Event (Other) ☐

Adverse Event (COVID-19  
infection) ☐

Death ☐

Lost To Follow-up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated By Sponsor ☐

Withdrawal of Consent (Other) ☐

Withdrawal of Consent  
(COVID-19 non-infection  
related) ☐

Other ☐

If reason is Adverse Event (Other), Physician Decision,  
Withdrawal of Consent (Other), Withdrawal of Consent  
(COVID-19 non-infection related), Protocol Deviation or Other,  
specify

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Visit Date**

**Generated On: 04 May 2021 23:11:23**

Was this visit performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Visit date (dd MMM yyyy)	<hr/>
Has participant been exposed or potentially exposed to COVID-19?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is participant COVID-19 symptomatic?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<i>Only record new symptoms since the last visit</i>	
Folder OID	<hr/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Unscheduled Visit Assessment**

**Generated On: 04 May 2021 23:11:23**

**Check all that apply**

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

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Vital Signs**

**Generated On: 04 May 2021 23:11:23**

Were vital signs assessed? Yes ☐  
No ☐

Date of assessment (*dd MMM yyyy*)

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

Fixed Unit: (24 HR)

Vital Signs Date and Time (derived)

Height (*xxx.x*)

cm ☐

in ☐

Weight (*xxx.x*)

kg ☐

lb ☐

BMI (*xxx.x*)

Fixed Unit: kg/m<sup>2</sup>

BMI units

Temperature (*xxx.x*)

C ☐

F ☐

Route of measurement

Oral ☐

Axillary ☐

Other ☐

If Other, specify

Pulse (*xxx*)

Fixed Unit: beats/min

Pulse units

Respiratory Rate (*xxx*)

Fixed Unit: breaths/min

Respiratory Rate units

Systolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Systolic Blood Pressure units

Diastolic Blood Pressure (*xxx*)

Fixed Unit: mmHg

Diastolic Blood Pressure units

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Central Laboratory**

**Generated On: 04 May 2021 23:11:23**

Collection date (dd MMM yyyy)

Lab panel Hematology ☒

Chemistry ☐

Serology ☐

Coagulation ☐

Was the sample collected? Yes ☐

No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐

Chemistry ☒

Serology ☐

Coagulation ☐

Was the sample collected? Yes ☐

No ☐

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

Collection date and time (derived)

Lab panel Hematology ☐

Chemistry ☐

Serology ☐

Coagulation ☒

Was the sample collected? Yes ☐

No ☐

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

Collection date and time (derived)

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

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

**Generated On: 04 May 2021 23:11:23**

Collection date (dd MMM yyyy)	
Lab Test	Nasopharyngeal Swab 1 <input checked="" type="checkbox"/>
	Nasopharyngeal Swab 2 <input type="checkbox"/>
	Blood Collection for exposure to SARS-CoV-2 <input type="checkbox"/>
Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection time (00:00 - 23:59)	
Collection date and time (derived)	
Lab Test	Nasopharyngeal Swab 1 <input type="checkbox"/>
	Nasopharyngeal Swab 2 <input checked="" type="checkbox"/>
	Blood Collection for exposure to SARS-CoV-2 <input type="checkbox"/>
Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection time (00:00 - 23:59)	
Collection date and time (derived)	
Lab Test	Nasopharyngeal Swab 1 <input type="checkbox"/>
	Nasopharyngeal Swab 2 <input type="checkbox"/>
	Blood Collection for exposure to SARS-CoV-2 <input checked="" type="checkbox"/>
Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection time (00:00 - 23:59)	
Collection date and time (derived)	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Pregnancy Test**

**Generated On: 04 May 2021 23:11:23**

Was the pregnancy test performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Date of test ( <i>dd MMM yyyy</i> )	
<hr/>	
Test performed	Urine <input type="checkbox"/>
	Serum <input type="checkbox"/>
<hr/>	
Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>
<hr/>	

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Central Laboratory - Antibody-Mediated Immunogenicity**

**Generated On: 04 May 2021 23:11:23**

Lab panel	Antibody-mediated Immunogenicity	<input checked="" type="radio"/>
Was the sample collected?	Yes	<input type="radio"/>
	No	<input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )		
Collection time ( <i>00:00-23:59</i> )	Fixed Unit: (24 HR)	
Collection date and time (derived)		

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Unscheduled**

**Form: Local Diagnostic Test**

**Generated On: 04 May 2021 23:11:23**

Date of Test	
Institution Name	
Diagnostic Test Performed	Nasopharyngeal Swab <input type="checkbox"/>
	Blood Test <input type="checkbox"/>
	Other <input type="checkbox"/>
Other, Specify	
Type of Diagnostic Test (if known):	
COVID-19 Result	Positive <input type="checkbox"/>
	Negative <input type="checkbox"/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 04 May 2021 23:11:23**

---

Did the participant experience any adverse events?

Yes ☐

No ☐

---

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

---

**PRODUCTION RELEASE (v10.002): MASTER****Folder: Adverse Events****Form: Adverse Events****Generated On: 04 May 2021 23:11:23**

Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	Fixed Unit: (24 HR)
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	Fixed Unit: (24 HR)
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/>
	Grade 2/Moderate <input type="checkbox"/>
	Grade 3/Severe <input type="checkbox"/>
	Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	
Congenital anomaly or birth defect	

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**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Adverse Events**

**Form: Adverse Events**

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Other medically important event	
Relationship to investigational product	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Relationship to Study Procedure	Not Related <input type="checkbox"/>
	Related <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Action taken with investigational product	None <input type="checkbox"/>
	Dose Delayed <input type="checkbox"/>
	Investigational Product <input type="checkbox"/>
	Withdrawn <input type="checkbox"/>
	Not Applicable <input type="checkbox"/>
Other action taken (check all that apply)	
None <input type="checkbox"/>	
Concomitant Medication <input type="checkbox"/>	
Concomitant Procedure <input type="checkbox"/>	
Outcome	Fatal <input type="checkbox"/>
	Not Recovered/Not Resolved <input type="checkbox"/>
	Recovered/Resolved <input type="checkbox"/>
	Recovered/Resolved with <input type="checkbox"/>
	Sequelae <input type="checkbox"/>
	Recovering/Resolving <input type="checkbox"/>
	Unknown <input type="checkbox"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Enter Narrative ONLY for Serious Adverse Events	
SAE Narrative	



**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Concomitant Medication and Vaccination**

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

**Generated On: 04 May 2021 23:11:23**

---

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

Yes ☐

No ☐

---

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

---

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**Folder: Concomitant Medication and Vaccination**

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

**Generated On: 04 May 2021 23:11:23**

Name of Medication	
Indication	
Dose per administration	
Dose unit	mg <input type="checkbox"/>
	ug <input type="checkbox"/>
	mL <input type="checkbox"/>
	g <input type="checkbox"/>
	IU <input type="checkbox"/>
	tablet <input type="checkbox"/>
	capsule <input type="checkbox"/>
	puff <input type="checkbox"/>
	Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/>
	twice daily <input type="checkbox"/>
	three times daily <input type="checkbox"/>
	four times daily <input type="checkbox"/>
	every other day <input type="checkbox"/>
	every week <input type="checkbox"/>
	every month <input type="checkbox"/>
	as needed <input type="checkbox"/>
	once <input type="checkbox"/>
	unknown <input type="checkbox"/>
	other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/>
	Topical <input type="checkbox"/>
	Subcutaneous <input type="checkbox"/>
	Transdermal <input type="checkbox"/>
	Intraocular <input type="checkbox"/>
	Intramuscular <input type="checkbox"/>
	Respiratory (Inhalation) <input type="checkbox"/>
	Intralesional <input type="checkbox"/>

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**Folder: Concomitant Medication and Vaccination**

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

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	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 _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

**PRODUCTION RELEASE (v10.002): MASTER**

**Folder: Concomitant Procedures**

**Form: Concomitant Procedures Summary**

**Generated On: 04 May 2021 23:11:23**

---

Were any concomitant procedures performed?

Yes ☐

No ☐

---

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

---

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**Folder: Concomitant Procedures**

**Form: Concomitant Procedures**

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

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**Folder: COVID-19 Impact**

**Form: COVID-19 Impact**

**Generated On: 04 May 2021 23:11:23**

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 8	<input type="checkbox"/>
	Visit 3 Day 15	<input type="checkbox"/>
	Visit 4 Day 29	<input type="checkbox"/>
	Visit 5 Day 36	<input type="checkbox"/>
	Visit 6 Day 43	<input type="checkbox"/>
	Visit 7 Day 57	<input type="checkbox"/>
	Visit 8 Day 209	<input type="checkbox"/>
	Visit 9 Day 394	<input type="checkbox"/>
	Participant Decision Visit /	<input type="checkbox"/>
	OL-D1	
	OL-D8	<input type="checkbox"/>
	OL-D15	<input type="checkbox"/>
	OL-D29	<input type="checkbox"/>
	OL-D57	<input type="checkbox"/>
	OL-D181	<input type="checkbox"/>
	OL-D209	<input type="checkbox"/>

**Case Report Form**

Visit Date	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory	
Central Laboratory with Serology	
Central Laboratory with FSH/Serology	
Central Laboratory - Nasopharyngeal Swab	
SARS-CoV-2 or COVID-19 Exposure Assessment	
SARS-CoV-2 or COVID-19 Symptoms Assessment	

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**Folder: COVID-19 Impact**

**Form: COVID-19 Impact**

**Generated On: 04 May 2021 23:11:23**

Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Central Laboratory - Antibody-Mediated Immunogenicity	
Safety Call	
Solicited Rash	
Lymphadenopathy	
Dosing Discontinuation	
End of Study / Study Discontinuation	
All	
Date of missed or out of window visit or assessment	
<b>Category</b>	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	
Visit performed out of window	
Assessment performed out of window	
Scheduled clinical visit performed as home visit	
Other	
Other, specify	
<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	
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

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**Folder: End of Study**

**Form: Dosing Discontinuation**

**Generated On: 04 May 2021 23:11:23**

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	Adverse Event (Other) <input type="checkbox"/>
	Adverse Event (COVID-19 infection) <input type="checkbox"/>
	Death <input type="checkbox"/>
	Lost To Follow-up <input type="checkbox"/>
	Physician Decision <input type="checkbox"/>
	Pregnancy <input type="checkbox"/>
	Protocol Deviation <input type="checkbox"/>
	Study Terminated By Sponsor <input type="checkbox"/>
	Withdrawal of Consent (Other) <input type="checkbox"/>
	Withdrawal of Consent (COVID-19 non-infection related) <input type="checkbox"/>
Other <input type="checkbox"/>	
If reason is Adverse Event (Other), Physician Decision, Withdrawal of Consent (Other), Withdrawal of Consent (COVID-19 non-infection related), Protocol Deviation or Other, specify	



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**Folder: End of Study**

**Form: End of Study / Study Discontinuation**

**Generated On: 04 May 2021 23:11:23**

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

Reason for discontinuation

Adverse Event (Other) ☐

Adverse Event (COVID-19  
infection) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated By Sponsor ☐

Withdrawal of Consent (Other) ☐

Withdrawal of Consent  
(COVID-19 non-infection  
related) ☐

Other ☐

If reason for discontinuation is Adverse Event (Other), Physician  
Decision, Withdrawal of Consent (Other), Withdrawal of Consent  
(COVID-19 non-infection related), Protocol Deviation, or Other,  
specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐