

US3602008 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:58:24

All time stamps listed in this document are displayed in GMT

US3602008

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

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[Participant ID](#)

US3602008

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

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US3602008

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3602008

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 20:55:22

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	2 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 20:55:22

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Condition	DM - 2010 - CONTROLLED WITH MEDICATIONS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 20:55:22

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Condition	ARTHRALGIAS OF BILATERAL HANDS AND FINGERS
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:05 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 14:05
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	193 lb
BMI ( <i>xxx.x</i> )	31.21615 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:55:22

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:55:22

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

EXECUTIVE FINANCIAL

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:55:22

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 20:55:23

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What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 145585

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☒   
 >=65 years ☐

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

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

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 20:55:23

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 14:05
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:56
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:55:22

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 SEP 2020

What was the treatment time? (00:00-23:59) 16:26 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 16:26

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	2 SEP 2020 14:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	2 SEP 2020 14:05
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °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

02 SEP 2020 16:46

PC Close Date & Time

02 SEP 2020 19:16

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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):

PC Time Stamp	03 SEP 2020 07:20
PC Open Date & Time	02 SEP 2020 20:11
PC Close Date & Time	03 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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):

PC Time Stamp

03 SEP 2020 12:17

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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):

PC Time Stamp

04 SEP 2020 15:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °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

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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):

PC Time Stamp

06 SEP 2020 13:30

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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):

PC Time Stamp

08 SEP 2020 10:20

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:24

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.4 °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):

PC Time Stamp

08 SEP 2020 14:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

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

02 SEP 2020 16:46

PC Close Date & Time

02 SEP 2020 19:16

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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 ☒

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

Yes ☐

No ☒

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

03 SEP 2020 07:20

PC Open Date & Time

02 SEP 2020 20:11

PC Close Date & Time

03 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 2

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 ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:18

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 3

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 ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:10

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 4

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 ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 5

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 ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 13:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 6

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 ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 10:20

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 7

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 ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 14:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 1, 30 MINUTES AFTER  
VACCINATION (AT STUDY  
CLINIC)

**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 ☐

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 16:46

PC Close Date & Time

02 SEP 2020 19:16

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**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 ☐

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 07:21
PC Open Date & Time	02 SEP 2020 20:11
PC Close Date & Time	03 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT

DAY 2

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 ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:18
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT

DAY 3

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 ☐

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

No ☒

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EAB) (1725)

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US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:24

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 15:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 4

**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 ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:24

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 5

**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 ☐

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

No ☒

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EAB) (1725)

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US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:24

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 13:32
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT

DAY 6

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 ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:24

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 10:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT

DAY 7

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 ☐

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

No ☒



US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:24

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 14:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3602008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

ATTEMPTS TO REACH PATIENT  
ON 9/16/20 FOR DAY #15  
MODERNA VACCINE SAFETY  
ASSESSMENT WERE MADE.

CALLS WERE MADE AT 6:15  
AND 7:11PM  
I WAS UNABLE TO REACH THE  
PATIENT.

INFO INSERTED PER EMR

US3602008

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2



US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	13:06 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 13:06
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER USED
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

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

US3602008

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was study treatment given? Yes ☐  
No ☒

If No, reason not given Participant declined due to ☒  
Adverse Event  
Physician withheld dose due to ☐  
Adverse Event  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by ☐  
Participant  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

Which arm was used to give treatment? Left Arm ☐  
Right Arm ☐

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3602008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	13:06 (24 HR)
Collection date and time (derived)	30 SEP 2020 13:06

US3602008

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:30	30 SEP 2020 13:30
Nasopharyngeal Swab 2	No		

US3602008

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

SUBJECT HAD AN A.E AND WAS  
FEELING ANXIOUS. SUBJECT  
DID NOT WANT TO RECEIVE  
INVESTIGATIONAL AGENT  
DOSE 2 BUT STILL IS  
CONTINUING ON WITH STUDY.



US3602008

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

SUBJECT HAD AN A.E AND WAS  
FEELING ANXIOUS. SUBJECT  
DID NOT WANT TO RECEIVE  
INVESTIGATIONAL AGENT  
DOSE 2 BUT STILL IS  
CONTINUING ON WITH STUDY.

US3602008

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

SUBJECT HAD AN A.E AND WAS  
FEELING ANXIOUS. SUBJECT  
DID NOT WANT TO RECEIVE  
INVESTIGATIONAL AGENT  
DOSE 2 BUT STILL IS  
CONTINUING ON WITH STUDY.

US3602008

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:22

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:54:00

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3602008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:54:00

Generated On: 11 Aug 2021 22:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:00
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602008

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:54:00

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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



US3602008

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

19 NOV 2020 11:00

US3602008

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:55:23

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3602008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3602008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 78

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

Date and time of submission

18 NOV 2020 12:01:11

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

---

20 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 NOV 2020 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 89

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

Date and time of submission

30 NOV 2020 08:21:31

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 00:12:46
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 103

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

Date and time of submission

13 DEC 2020 17:09:28

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 110

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

Date and time of submission

18 DEC 2020 06:49:30

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 117

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

Date and time of submission

26 DEC 2020 14:11:13

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
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 <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 22:17:26
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 131

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

Date and time of submission

08 JAN 2021 08:26:00

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 138

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

Date and time of submission

15 JAN 2021 07:59:16

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 145

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

Date and time of submission

22 JAN 2021 09:24:47

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 152

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

Date and time of submission

29 JAN 2021 07:44:18

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 159

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

Date and time of submission

06 FEB 2021 13:19:48

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 173

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

Date and time of submission

19 FEB 2021 09:25:20

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 180

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

Date and time of submission

26 FEB 2021 13:46:23

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 187

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

Date and time of submission

09 MAR 2021 13:22:04

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 194

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

Date and time of submission

15 MAR 2021 15:21:43

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 201

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

Date and time of submission

19 MAR 2021 10:03:23

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 208

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

Date and time of submission

26 MAR 2021 11:45:47

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 215

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

Date and time of submission

02 APR 2021 08:55:45

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 222

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

Date and time of submission

09 APR 2021 02:04:16

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 257

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 313

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 327

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 341

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°F/38°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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 355

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°F/38°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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 383

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 397

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 404

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 418

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 432

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 446

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 467

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 474

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°F/38°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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 502

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°F/38°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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 509

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 523

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

04 FEB 2022 00:01

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08 FEB 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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15 FEB 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT

DAY 537

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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22 FEB 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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25 FEB 2022 00:01

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01 MAR 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 551

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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08 MAR 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 558

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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11 MAR 2022 00:01

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15 MAR 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 565

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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18 MAR 2022 00:01

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22 MAR 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 572

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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25 MAR 2022 00:01

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29 MAR 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 579

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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01 APR 2022 00:01

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05 APR 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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08 APR 2022 00:01

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12 APR 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 593

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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26 APR 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 642

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°F/38°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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 649

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 663

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 670

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT

DAY 677

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 684

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 698

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

26 AUG 2022 00:01

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30 AUG 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
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 <input type="checkbox"/>
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 <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 SEP 2022 00:01

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20 SEP 2022 23:59

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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 754

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

23 SEP 2022 00:01

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27 SEP 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 761

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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30 SEP 2022 00:01

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04 OCT 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
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 <input type="radio"/>
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 <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
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 <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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

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07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 775

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 782

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°F/38°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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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 <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59
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US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 789

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59



US3602008

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

DAY 796

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 ☐

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3602008

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:58:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 14:16:56

US3602008

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

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*

MISSED SAFETY CALL DUE TO  
LACK OF CLARIFICATION OF  
EUA PROTOCOL FOR  
COMBINING SAFETY CALLS  
FROM PART A AND PART B.



US3602008

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 01:32:49

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 01:32:49

Generated On: 11 Aug 2021 22:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 APR 2021
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 12:35
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602008

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 01:32:49

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 APR 2021

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

US3602008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 01:32:49

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 APR 2021
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	9 APR 2021 12:45

US3602008

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3602008**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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*

**US3602008**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3602008**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:58:24**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3602008**

**Folder: Covid-19 Assessment (1)**

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

**Generated On: 11 Aug 2021 22:58:24**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Date of updated informed consent ( <i>dd MMM yyyy</i> )	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	6 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 14:45
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG



US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 JAN 2021
Time of assessment (00:00-23:59)	17:15 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 17:15
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

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

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 JAN 2021

What was the treatment time? (00:00-23:59) 16:45 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 16:45

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	15:25 (24 HR)
Collection date and time (derived)	6 JAN 2021 15:25

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	15:05
Collection Date and Time (derived)	6 JAN 2021 15:05

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3602008

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3602008

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 14:36
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3602008

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 FEB 2021
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	4 FEB 2021 16:30
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3602008

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 FEB 2021

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

US3602008

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 4 FEB 2021

What was the treatment time? (00:00-23:59) 16:00 (24 HR)

Treatment Date and Time (derived) 4 FEB 2021 16:00

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3602008

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602008

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602008

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:06:53

Generated On: 11 Aug 2021 22:58:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3602008

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3602008

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 MAR 2021
Time of assessment (00:00-23:59)	12:25 (24 HR)
Vital Signs Date and Time (derived)	4 MAR 2021 12:25
Temperature (xxx.x)	97 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602008

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 MAR 2021

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

US3602008

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	4 MAR 2021
Collection time ( <i>00:00-23:59</i> )	12:30 (24 HR)
Collection date and time (derived)	4 MAR 2021 12:30

US3602008

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

AEID	
Adverse event	WORSENING JOINT ACHES OR PAIN LOCATED IN BILATERAL SHOULDER AND HANDS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	9 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

---

ONSET DATE: D# 8 POST  
VACCINE  
SEVERITY: MILD  
ACTION TAKEN: TOOK  
CELBREX PRN ONCE DAILY  
INITIALLY THEN EVERY OTHER  
DAY DURING WEEK 3  
· RESOLUTION: RESOLUTION  
OF SHOULDER PAIN BY WEEK  
3. IMPROVEMENT IN HAND  
STIFFNESS BY WEEK 4.  
OUTCOME: RESIDUAL MILD  
HAND STIFFNESS  
· ANY MEDS TAKEN :  
CELEBREX.  
· ANY MEDICAL ATTN FOR THE  
AE: NO  
LEFT MESSAGE TO HAVE PT  
RETURN CALL

1. I AM AWARE THAT HE  
WOULD LIKE NOT TO PROCEED  
WITH THE SECOND SHOT : I  
WANTED TO CONFIRM THE  
SAME  
2. WANTED TO FIND OUT HIW  
HIS S/S WERE TODAY ( ARTHRALGIAS)  
3. WANTED TO SEE IF THE  
PATIENT WOULD LIKE TO  
PARTICIPATE IN THE REST OF  
THE FOLLOW UP WITH THE  
REMAINDER OF THE BLOOD  
DRWAS AND SAFETY CALL  
FOLLOW UP OVER THE NEXT 24  
MONTHS

ASKED HIM TO CALL BACK  
THE COVID VACCINE HOT LINE

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
--	---

Medically Attended AE Derived (CSA Programming Field Only)	0
--	---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

---



US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

AEID

Adverse event

ANXIETY DUE THE SIDE  
EFFECTS OF THE FIRST IP

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

8 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

---

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

Yes ☒

No ☐

---

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

---

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Name of Medication JANUMET

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS

Dose per administration 1000/50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	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)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Name of Medication RAMAPRIL

Prophylaxis Yes ☐  
No ☒

Indication FOR HYPERTENSION

Dose per administration 1.25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	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		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Name of Medication ROSUVASTIN

Prophylaxis Yes ☒  
No ☐

Indication FOR HYPERLIPIDEMIA

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	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		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Name of Medication VITAMIN B 12

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL NEEDS/DIETARY SUPPLEMENT

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	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		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL NEEDS/DIETARY SUPPLEMENT

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	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		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Name of Medication CELBREX

Prophylaxis Yes ☐  
No ☒

Indication TO TREAT A.E-  
WORSENING JOINT ACHES OR  
PAIN LOCATED IN BILATERAL  
SHOULDER AND HANDS  
REPORTED ON DAY 21 ON 9/23

Dose per administration 200

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

ONCE DAILY PRN, IN PM

Route of administration Oral ☒  
Topical ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

	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"/>
	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)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3602008

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



US3602008

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Apr 2021 20:56:18

Generated On: 11 Aug 2021 22:58:24

---

Date of dosing discontinuation (dd MMM yyyy) 30 SEP 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #2

---

US3602008

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Feb 2021 22:06:52

Generated On: 11 Aug 2021 22:58:24

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, 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 ☐

Audit

US3602008 (Prod: Hackensack University Medical Center)

**US3602008**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:58:24**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:38:10
User entered 'US3602008'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:39:45

**US3602008**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:43:36

**US3602008**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:39:46

**US3602008**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:43:36

**US3602008**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'SCRN'	System	02 Sep 2020 19:43:36



US3602008

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:58:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:39:47

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '62'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'YEARS'	System	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered '62'	System	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52



**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:58:24**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:44:52

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:00



**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'Sep 2020'	System	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered '2020'	System	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:00

**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:39:46



**US3602008**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:58:24**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'I'	System	02 Sep 2020 19:46:13

**US3602008**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:58:24**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 19:46:13

**US3602008**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:58:24**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 20:25:12
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 19:50:26

US3602008

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:58:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:28:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:28:51
Data point term sent to Coder	System	17 Sep 2020 20:26:12
User entered 'DM - 2010 - Controlled with medications'	(b) (4), (b) (6)	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:25:40



**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'Jan 2010'	System	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered '2010'	System	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	17 Sep 2020 20:25:40

**US3602008**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	17 Sep 2020 20:25:40

US3602008

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:58:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per DM CLR: Please specify the location of ARTHRALGIAS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:31:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in joint involving hand - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 21:41:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 21:41:58
Data point term sent to Coder	System	13 Jan 2021 15:20:33
Query 'Per DM CLR: Please specify the location of ARTHRALGIAS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 15:20:32
Coding entries removed.	(b) (4), (b) (6)	13 Jan 2021 15:20:23
User entered 'ARTHRALGIAS of bilateral hands and fingers' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Jan 2021 15:20:23
User opened query 'Per DM CLR: Please specify the location of ARTHRALGIAS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:49:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:16:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:16:26
Data point term sent to Coder	System	28 Oct 2020 20:27:22

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Condition](#)

Audit	User	Time (GMT)
User entered 'Arthralgias - as per HPI'	(b) (4), (b) (6)	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:27:01



**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	28 Oct 2020 20:27:01

**US3602008**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	28 Oct 2020 20:27:01



US3602008

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:58:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:19:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 07:19:54
Data point term sent to Coder	System	16 Nov 2020 20:36:23
User entered 'Hyperlipidemia (HL)'	(b) (4), (b) (6)	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:03



**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:03

**US3602008**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:03

US3602008

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:58:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:37:47
Data point term sent to Coder	System	16 Nov 2020 20:37:24
User entered 'Hypertension (HTN)'	(b) (4), (b) (6)	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:36:36



**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered empty.	System	16 Nov 2020 20:36:36

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:01:54

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Sep 2020 21:10:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Sep 2020 21:10:34
User entered '14:05' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 21:10:34
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:01:54
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered '2 Sep 2020 14:05'	System	02 Sep 2020 21:10:34
User entered empty.	System	02 Sep 2020 20:01:54



**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '66' in	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:01:54
DataPoint set to visible.	System	02 Sep 2020 19:46:13

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '193' lb	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:01:54
DataPoint set to visible.	System	02 Sep 2020 19:46:13

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered '31.21615'	System	02 Sep 2020 20:01:54
DataPoint set to visible.	System	02 Sep 2020 19:46:13

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'kg/m2'	System	02 Sep 2020 20:01:54
DataPoint set to visible.	System	02 Sep 2020 19:46:13

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 03:49:11
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:15:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:14:53
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:41:21
User entered '97.6' F	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:14:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:01:54

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND - 'Not Done' should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:37:56
Query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND - 'Not Done' should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' answered with 'Updated per query' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 20:05:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 20:05:11
User opened query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND - 'Not Done' should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:24:54
Query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day (11 SEP 2020), Not done (ND) should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:24:25



US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Pulse (xxx)

Audit	User	Time (GMT)
User opened query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day (11 SEP 2020), Not done (ND) should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:11:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 14:10:33
Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 22:35:49
User opened query 'Data is required. Please provide.' System (Site from System).		08 Oct 2020 22:35:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 22:35:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:14:53
User entered '64'	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'bpm'	System	09 Oct 2020 20:05:11
User entered empty.	System	08 Oct 2020 22:35:44
User entered 'bpm'	System	02 Sep 2020 20:01:54

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 20:05:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 14:10:36
Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 22:35:52
User opened query 'Data is required. Please provide.' System (Site from System).		08 Oct 2020 22:35:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 22:35:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:14:53
User entered '16'	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'breaths/min'	System	09 Oct 2020 20:05:11
User entered empty.	System	08 Oct 2020 22:35:44
User entered 'breaths/min'	System	02 Sep 2020 20:01:54

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 20:05:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 14:10:40
Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 22:35:55
User opened query 'Data is required. Please provide.' System (Site from System).		08 Oct 2020 22:35:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 22:35:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:14:53
User entered '124'	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'mmHg'	System	09 Oct 2020 20:05:11
User entered empty.	System	08 Oct 2020 22:35:44
User entered 'mmHg'	System	02 Sep 2020 20:01:54

US3602008

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	09 Oct 2020 20:05:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 14:10:42
Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 22:35:58
User opened query 'Data is required. Please provide.' System (Site from System).		08 Oct 2020 22:35:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 22:35:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:14:53
User entered '78'	(b) (4), (b) (6)	02 Sep 2020 20:01:54

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User entered 'mmHg'	System	09 Oct 2020 20:05:11
User entered empty.	System	08 Oct 2020 22:35:44
User entered 'mmHg'	System	02 Sep 2020 20:01:54



**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34

**US3602008**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34

**US3602008**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:02:29

**US3602008**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:02:29

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

**US3602008**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:58:24**

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40



US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

**US3602008**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:58:24**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40



**US3602008**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Executive Financial'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

**US3602008**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:58:24**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

US3602008

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:58:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

**US3602008**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:58:24**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40



**US3602008**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:34
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:05:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:06:32

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:06:32

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:06:32

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'VISIT1'	System	02 Sep 2020 20:06:32

US3602008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:34:41

US3602008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '145585'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:34:41

US3602008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:34:41



**US3602008**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:10:32

US3602008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:10:32

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:58:24**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:10:32

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:58:24**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:10:32

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:58:24**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:10:32

US3602008

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:58:24

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:38:54
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:55:03
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 20:54:59
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:41:03
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:58:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:58:05

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 10:16:37
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:15:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:15:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:40:53
User entered '66' in	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:15:20
User entered '193' lb	(b) (4), (b) (6)	02 Sep 2020 20:12:38



US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 10:16:37
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:15:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:15:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:40:53
User entered '66' in	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 20:15:20
User entered '193' lb	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	02 Sep 2020 21:12:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	02 Sep 2020 21:12:53
User entered '14:05' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 21:12:53
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:12:38
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '2 Sep 2020 14:05'	System	02 Sep 2020 21:12:53
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	09 Sep 2020 18:54:37
User entered '97.6' F reason for change: Data Entry Error	System	09 Sep 2020 18:54:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 18:54:37
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Sep 2020 18:53:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 18:53:56
User entered '97.6' (non-conformant).	System	09 Sep 2020 18:53:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 20:12:38
User entered empty.	System	02 Sep 2020 20:12:38



US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:53:56
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 18:53:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 18:53:56
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 18:53:56
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:12:38
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'bpm'	System	09 Sep 2020 18:53:56
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	09 Sep 2020 18:53:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 18:53:56
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 18:53:56
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:12:38
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'breaths/min'	System	09 Sep 2020 18:53:56
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 18:53:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 18:53:56
User entered '124' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 18:53:56
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:12:38
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	09 Sep 2020 18:53:56
User entered empty.	System	02 Sep 2020 20:12:38



US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 18:53:56
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 18:53:56
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 18:53:56
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 20:12:38
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	09 Sep 2020 18:53:56
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:24

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 10:16:37
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 20:15:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:15:20
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 22:40:53
User entered '66' in	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:58:24

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 20:15:20
User entered '193' lb	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Sep 2020 21:12:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 21:12:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 21:12:53
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:12:38
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 16:26, and time of Assessment is 16:26. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:04:54
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 16:26, and time of Assessment is 16:26. Please review and update or provide a clarification. Thank you' answered with 'TIME UPDATED PER EMR/EHR' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:00:54
User entered '16:56' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:00:47
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 16:26, and time of Assessment is 16:26. Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:41:24
User entered '16:26' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38



**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '2 Sep 2020 16:56'	System	21 Sep 2020 18:00:47
User entered '2 Sep 2020 16:26'	System	02 Sep 2020 21:12:53
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 19:26:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 19:26:39
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:26:39
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 19:26:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 19:26:39
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'bpm'	System	09 Sep 2020 19:26:39
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	09 Sep 2020 19:26:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	09 Sep 2020 19:26:39
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'breaths/min'	System	09 Sep 2020 19:26:39
User entered empty.	System	02 Sep 2020 20:12:38



US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	09 Sep 2020 19:26:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 19:26:39
User entered '102' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	09 Sep 2020 19:26:39
User entered empty.	System	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	09 Sep 2020 19:26:39
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Sep 2020 19:26:39
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 19:26:39
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Sep 2020 21:12:53
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 20:12:38

US3602008

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	09 Sep 2020 19:26:39
User entered empty.	System	02 Sep 2020 20:12:38

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:12:57

US3602008

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:12:57

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:28:57

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:28:57



US3602008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:28:57

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 20:28:57

US3602008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:28:57

US3602008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '16:26'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:28:57

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '2 Sep 2020 16:26'	System	02 Sep 2020 20:28:57

US3602008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:28:57

US3602008

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'ONCE'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 20:28:57



**US3602008**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:11:46

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:11:46

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '14:05'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:11:46

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '2 Sep 2020 14:05'	System	04 Sep 2020 16:11:46

US3602008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:12:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 16:12:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:12:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '14:05'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:12:40



**US3602008**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '2 Sep 2020 14:05'	System	04 Sep 2020 16:12:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 16:12:40

US3602008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 21:13:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 21:13:47
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:12:40
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:12:40

US3602008

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:58:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:12:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	04 Sep 2020 16:12:40

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:12:48

**US3602008**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	04 Sep 2020 16:12:48

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:28:57



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 16:46'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 19:16'	System	02 Sep 2020 20:28:57



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:19:56', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c82fb87b-b2c0-4218-b59f-22011fb8e248' User entered 'Yes (Y)'	System	03 Sep 2020 11:20:22
	System	03 Sep 2020 11:20:22

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:05', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c82fb87b-b2c0-4218-b59f-22011fb8e248' User entered '97.6'	System	03 Sep 2020 11:20:22
	System	03 Sep 2020 11:20:22

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:10', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c82fb87b-b2c0-4218-b59f-22011fb8e248' User entered 'No (N)'	System	03 Sep 2020 11:20:22
	System	03 Sep 2020 11:20:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:20', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c82fb87b-b2c0-4218-b59f-22011fb8e248' User entered '03 Sep 2020 07:20'	System	03 Sep 2020 11:20:22
	System	03 Sep 2020 11:20:22

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 2'	System	02 Sep 2020 20:28:57



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:17:36', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'e548694d-5dcd-48c6-8662-d1e88b306338' User entered 'Yes (Y)'	System	03 Sep 2020 16:17:59
	System	03 Sep 2020 16:17:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:17:46', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'e548694d-5dcd-48c6-8662-d1e88b306338' User entered '97.4'	System	03 Sep 2020 16:17:59
	System	03 Sep 2020 16:17:59

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:17:50', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'e548694d-5dcd-48c6-8662-d1e88b306338'	System	03 Sep 2020 16:17:59
User entered 'No (N)'	System	03 Sep 2020 16:17:59

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:17:58', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'e548694d-5dcd-48c6-8662-d1e88b306338' User entered '03 Sep 2020 12:17'	System	03 Sep 2020 16:17:59
	System	03 Sep 2020 16:17:59

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 3'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:09:39', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '309f8a90-a5e6-4497-814b-5ebf949c4507' User entered 'Yes (Y)'	System	04 Sep 2020 19:10:01
	System	04 Sep 2020 19:10:01



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:09:47', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '309f8a90-a5e6-4497-814b-5ebf949c4507' User entered '97.5'	System	04 Sep 2020 19:10:01
	System	04 Sep 2020 19:10:01

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:09:51', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '309f8a90-a5e6-4497-814b-5ebf949c4507'	System	04 Sep 2020 19:10:01
User entered 'No (N)'	System	04 Sep 2020 19:10:01

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:09:57', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '309f8a90-a5e6-4497-814b-5ebf949c4507' User entered '04 Sep 2020 15:09'	System	04 Sep 2020 19:10:01
	System	04 Sep 2020 19:10:01

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 4'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 5'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:29:49', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f2a24f3e-991b-43db-a03d-34629b688a70' User entered 'Yes (Y)'	System	06 Sep 2020 17:30:40
	System	06 Sep 2020 17:30:40



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:30:28', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f2a24f3e-991b-43db-a03d-34629b688a70' User entered '98.0'	System	06 Sep 2020 17:30:40
	System	06 Sep 2020 17:30:40

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:30:32', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f2a24f3e-991b-43db-a03d-34629b688a70'	System	06 Sep 2020 17:30:40
User entered 'No (N)'	System	06 Sep 2020 17:30:40

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:30:37', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f2a24f3e-991b-43db-a03d-34629b688a70' User entered '06 Sep 2020 13:30'	System	06 Sep 2020 17:30:40
	System	06 Sep 2020 17:30:40

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 6'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:18', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c2cd8d80-cd78-49a8-8ca7-f24a695a6d2b' User entered 'Yes (Y)'	System	08 Sep 2020 14:20:36
	System	08 Sep 2020 14:20:36

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:24', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c2cd8d80-cd78-49a8-8ca7-f24a695a6d2b' User entered '97.3'	System	08 Sep 2020 14:20:36
	System	08 Sep 2020 14:20:36



US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:28', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c2cd8d80-cd78-49a8-8ca7-f24a695a6d2b' User entered 'No (N)'	System	08 Sep 2020 14:20:36
	System	08 Sep 2020 14:20:36

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:33', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c2cd8d80-cd78-49a8-8ca7-f24a695a6d2b' User entered '08 Sep 2020 10:20'	System	08 Sep 2020 14:20:36
	System	08 Sep 2020 14:20:36

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 7'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:13', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '00b8f75d-3621-4537-9ef1-33fd400dc52a' User entered 'Yes (Y)'	System	08 Sep 2020 18:01:31
	System	08 Sep 2020 18:01:31

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:19', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '00b8f75d-3621-4537-9ef1-33fd400dc52a' User entered '95.4'	System	08 Sep 2020 18:01:31
	System	08 Sep 2020 18:01:31

US3602008

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:58:24

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:24', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '00b8f75d-3621-4537-9ef1-33fd400dc52a' User entered 'No (N)'	System	08 Sep 2020 18:01:31
	System	08 Sep 2020 18:01:31



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:29', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '00b8f75d-3621-4537-9ef1-33fd400dc52a' User entered '08 Sep 2020 14:01'	System	08 Sep 2020 18:01:31
	System	08 Sep 2020 18:01:31

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 16:46'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 19:16'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:29', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'd3e207dd-f023-4d9b-8245-1d1d399ca569' User entered 'None (1)'	System	03 Sep 2020 11:20:46
	System	03 Sep 2020 11:20:46

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:33', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'd3e207dd-f023-4d9b-8245-1d1d399ca569' User entered 'No (N)'	System	03 Sep 2020 11:20:46
	System	03 Sep 2020 11:20:46



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:35', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'd3e207dd-f023-4d9b-8245-1d1d399ca569' User entered 'No (N)'	System	03 Sep 2020 11:20:46
	System	03 Sep 2020 11:20:46

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:40', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'd3e207dd-f023-4d9b-8245-1d1d399ca569' User entered 'None (1)'	System	03 Sep 2020 11:20:46
	System	03 Sep 2020 11:20:46

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'd3e207dd-f023-4d9b-8245-1d1d399ca569' User entered '03 Sep 2020 07:20'	System	03 Sep 2020 11:20:46
	System	03 Sep 2020 11:20:46

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 2'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:41', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eec10cd7-a83e-4e53-b755-03cde11c4b23'	System	03 Sep 2020 16:19:02
User entered 'None (1)'	System	03 Sep 2020 16:19:02

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:45', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eec10cd7-a83e-4e53-b755-03cde11c4b23' User entered 'No (N)'	System	03 Sep 2020 16:19:02
	System	03 Sep 2020 16:19:02



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:53', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eec10cd7-a83e-4e53-b755-03cde11c4b23' User entered 'No (N)'	System	03 Sep 2020 16:19:02
	System	03 Sep 2020 16:19:02

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:56', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eec10cd7-a83e-4e53-b755-03cde11c4b23'	System	03 Sep 2020 16:19:02
User entered 'None (1)'	System	03 Sep 2020 16:19:02

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:59', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eec10cd7-a83e-4e53-b755-03cde11c4b23' User entered '03 Sep 2020 12:18'	System	03 Sep 2020 16:19:02
	System	03 Sep 2020 16:19:02

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 3'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:07', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'ae59e616-5550-4aa3-b98e-85fc4802b02d' User entered 'None (1)'	System	04 Sep 2020 19:10:23
	System	04 Sep 2020 19:10:23

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:10', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'ae59e616-5550-4aa3-b98e-85fc4802b02d' User entered 'No (N)'	System	04 Sep 2020 19:10:23
	System	04 Sep 2020 19:10:23



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:13', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'ae59e616-5550-4aa3-b98e-85fc4802b02d' User entered 'No (N)'	System	04 Sep 2020 19:10:23
	System	04 Sep 2020 19:10:23

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:17', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'ae59e616-5550-4aa3-b98e-85fc4802b02d' User entered 'None (1)'	System	04 Sep 2020 19:10:23
	System	04 Sep 2020 19:10:23

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:20', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'ae59e616-5550-4aa3-b98e-85fc4802b02d' User entered '04 Sep 2020 15:10'	System	04 Sep 2020 19:10:23
	System	04 Sep 2020 19:10:23

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 4'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:58:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 5'	System	02 Sep 2020 20:28:57



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:30:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eaac4522-6fec-498b-8a32-ca140e299aff' User entered 'None (1)'	System	06 Sep 2020 17:31:23
	System	06 Sep 2020 17:31:23

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:30:54', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eaac4522-6fec-498b-8a32-ca140e299aff' User entered 'No (N)'	System	06 Sep 2020 17:31:23
	System	06 Sep 2020 17:31:23

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:31:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eaac4522-6fec-498b-8a32-ca140e299aff' User entered 'No (N)'	System	06 Sep 2020 17:31:23
	System	06 Sep 2020 17:31:23

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:31:13', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eaac4522-6fec-498b-8a32-ca140e299aff' User entered 'None (1)'	System	06 Sep 2020 17:31:23
	System	06 Sep 2020 17:31:23

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:31:21', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'eaac4522-6fec-498b-8a32-ca140e299aff' User entered '06 Sep 2020 13:31'	System	06 Sep 2020 17:31:23
	System	06 Sep 2020 17:31:23

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 6'	System	02 Sep 2020 20:28:57



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:37', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b5b668c2-2e11-413e-b5c3-797d41e2aac8'	System	08 Sep 2020 14:20:53
User entered 'None (1)'	System	08 Sep 2020 14:20:53

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:41', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b5b668c2-2e11-413e-b5c3-797d41e2aac8' User entered 'No (N)'	System	08 Sep 2020 14:20:53
	System	08 Sep 2020 14:20:53

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b5b668c2-2e11-413e-b5c3-797d41e2aac8' User entered 'No (N)'	System	08 Sep 2020 14:20:53
	System	08 Sep 2020 14:20:53

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:48', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b5b668c2-2e11-413e-b5c3-797d41e2aac8'	System	08 Sep 2020 14:20:53
User entered 'None (1)'	System	08 Sep 2020 14:20:53

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:20:51', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b5b668c2-2e11-413e-b5c3-797d41e2aac8' User entered '08 Sep 2020 10:20'	System	08 Sep 2020 14:20:53
	System	08 Sep 2020 14:20:53

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 7'	System	02 Sep 2020 20:28:57



US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:37', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7aa61733-9352-4bfb-9f3a-c4a9b7d6a6e9' User entered 'None (1)'	System	08 Sep 2020 18:01:52
	System	08 Sep 2020 18:01:52

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:41', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7aa61733-9352-4bfb-9f3a-c4a9b7d6a6e9' User entered 'No (N)'	System	08 Sep 2020 18:01:52
	System	08 Sep 2020 18:01:52

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7aa61733-9352-4bfb-9f3a-c4a9b7d6a6e9' User entered 'No (N)'	System	08 Sep 2020 18:01:52
	System	08 Sep 2020 18:01:52

US3602008

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:58:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:47', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7aa61733-9352-4bfb-9f3a-c4a9b7d6a6e9' User entered 'None (1)'	System	08 Sep 2020 18:01:52
	System	08 Sep 2020 18:01:52

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:50', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7aa61733-9352-4bfb-9f3a-c4a9b7d6a6e9' User entered '08 Sep 2020 14:01'	System	08 Sep 2020 18:01:52
	System	08 Sep 2020 18:01:52

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:28:57



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 16:46'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 19:16'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:50', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'None (0)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:20:59', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'None (0)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:21:02', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'None (0)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:21:06', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'None (0)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:21:09', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'None (0)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:21:11', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'None (0)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:21:15', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered 'No (N)'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T07:21:20', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '8f56f55b-961c-4eb8-ac63-82fcf008f960' User entered '03 Sep 2020 07:21'	System	03 Sep 2020 11:21:22
	System	03 Sep 2020 11:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '02 Sep 2020 20:11'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 2'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:09', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'None (0)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:12', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'None (0)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35



US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:15', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'None (0)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:18', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'None (0)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:21', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'None (0)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:24', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'None (0)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:30', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered 'No (N)'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-03T12:18:32', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'f57d406f-f9f9-4c44-a076-de1ca13700d9' User entered '03 Sep 2020 12:18'	System	03 Sep 2020 16:18:35
	System	03 Sep 2020 16:18:35

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:28:57



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 3'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:25', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'None (0)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:24

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:28', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'None (0)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:30', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'None (0)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:33', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'None (0)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:36', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'None (0)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:38', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'None (0)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:42', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered 'No (N)'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-04T15:10:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '9757e33a-8d24-4af8-b7c5-d4940248d7a1' User entered '04 Sep 2020 15:10'	System	04 Sep 2020 19:10:46
	System	04 Sep 2020 19:10:46

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 4'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15



US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:24

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 5'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:31:46', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'None (0)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:31:50', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'None (0)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:32:34', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'None (0)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:32:37', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'None (0)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:32:39', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'None (0)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:32:42', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'None (0)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:32:45', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered 'No (N)'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-06T13:32:48', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3875dc3c-2809-4d4e-af58-473fcd10f7f9' User entered '06 Sep 2020 13:32'	System	06 Sep 2020 17:32:51
	System	06 Sep 2020 17:32:51

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:28:57



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 6'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'None (0)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:03', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'None (0)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:06', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'None (0)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:24

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:08', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'None (0)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:11', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'None (0)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:13', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'None (0)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22



US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:18', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered 'No (N)'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T10:21:20', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '88e328f9-7201-4136-bc55-5022b8bc7286' User entered '08 Sep 2020 10:21'	System	08 Sep 2020 14:21:22
	System	08 Sep 2020 14:21:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 7'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:55', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'None (0)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:01:58', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'None (0)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:24

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:02:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'None (0)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22



**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:02:03', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'None (0)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:02:09', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'None (0)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:02:12', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'None (0)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

US3602008

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:02:17', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered 'No (N)'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-09-08T14:02:20', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cc19d514-5329-416e-9a6b-0a3bce5346be' User entered '08 Sep 2020 14:02'	System	08 Sep 2020 18:02:22
	System	08 Sep 2020 18:02:22

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:58:24**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:41:36



**US3602008**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:41:36

**US3602008**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:41:36

US3602008

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Per DM CLR: Review specified comment, JOINT ACHES OR PAIN - Y. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:09:42
Query 'Per DM CLR: Review specified comment, JOINT ACHES OR PAIN - Y. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate.' answered with 'AE page updated' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:01:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 19:01:16
User opened query 'Per DM CLR: Review specified comment, JOINT ACHES OR PAIN - Y. Verify if this condition meets AE reporting criteria. If yes, update AE page as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Sep 2020 09:40:05
User entered 'Joint aches or pain - y.	(b) (4), (b) (6)	11 Sep 2020 16:41:36
Tylenol (dose) : none taken.		
Ediary completed.		
Info inserted per EMR/EHR'		

**US3602008**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:41:42

**US3602008**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	11 Sep 2020 16:41:42

**US3602008**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:37:59

**US3602008**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:37:59

**US3602008**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:37:59



US3602008

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Attempts to reach patient on 9/16/20 for day #15 Moderna vaccine safety assessment were made.'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:37:59

Calls were made at 6:15 and 7:11PM

I was unable to reach the patient.

Info inserted per EMR'

**US3602008**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 16:39:32

**US3602008**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	25 Sep 2020 16:39:32

**US3602008**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:14:41

US3602008

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	25 Sep 2020 18:15:03
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Sep 2020 18:15:03
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 18:15:03
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 18:14:41
User entered '22 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 18:14:41

**US3602008**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:14:41

**US3602008**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:14:41

**US3602008**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 18:15:18



**US3602008**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	25 Sep 2020 18:15:18

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:52:21

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:52:21

US3602008

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:52:21

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'VISIT2'	System	30 Sep 2020 19:52:21

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17



**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '13:06'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '30 Sep 2020 13:06'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Temporal/Forehead scanner used'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '57'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'bpm'	System	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17



US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'breaths/min'	System	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '124'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '80'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '30 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 19:55:17



**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '13:45'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	12 Oct 2020 19:58:42
User entered '30 Sep 2020 13:45'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '97.5' F	(b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered 'Other (Other)'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered 'Temporal/Forehead scanner used'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '52'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	12 Oct 2020 19:58:42
User entered 'bpm'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '16'	(b) (4), (b) (6)	30 Sep 2020 19:55:17



**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	12 Oct 2020 19:58:42
User entered 'breaths/min'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '129'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	12 Oct 2020 19:58:42
User entered 'mmHg'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Oct 2020 19:58:42
User entered '80'	(b) (4), (b) (6)	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	12 Oct 2020 19:58:42
User entered 'mmHg'	System	30 Sep 2020 19:55:17

US3602008

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:56:20

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:56:20

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:41:37



US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:56:06
User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Oct 2020 16:09:39
Query 'Per CDM: Re query: Thank you for the response, please note that study treatment given 'No' mentioned as 'Participant declined due to Adverse Event'. Kindly update the AE page for dose interruptions or else please clarify the reason for subject withdrawal accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:58:26
User opened query 'Per CDM: Re query: Thank you for the response, please note that study treatment given 'No' mentioned as 'Participant declined due to Adverse Event'. Kindly update the AE page for dose interruptions or else please clarify the reason for subject withdrawal accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:56:02
Query 'Per CDM: Re query: Thank you for the response, please note that study treatment given No as stated as 'Participant declined due to Adverse Event'. Kindly update the AE page for dose delay and interruptions or else update the exact reason for subject withdrawal.' canceled (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:53:35
User opened query 'Per CDM: Re query: Thank you for the response, please note that study treatment given No as stated as 'Participant declined due to Adverse Event'. Kindly update the AE page for dose delay and interruptions or else update the exact reason for subject withdrawal.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:47:04
User closed query 'Per CDM: V2 D29 Study treatment was not given; however, AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify'. (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:47:04

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

If No, reason not given

Audit	User	Time (GMT)
Query 'Per CDM: V2 D29 Study treatment was not given; however, AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' answered with 'Subject withdrew from study per (b) (6) info acquired via email from onsite DC on 10/12/2020 @15:37' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 20:03:48
User opened query 'Per CDM: V2 D29 Study treatment was not given; however, AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify".' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 11:27:59
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4), (b) (6)	30 Sep 2020 19:41:37

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:41:37

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	30 Sep 2020 19:41:37

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:41:37

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:41:37

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	30 Sep 2020 19:41:37

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:41:37



US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	30 Sep 2020 19:41:37

US3602008

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	30 Sep 2020 19:41:37

US3602008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:56:52

US3602008

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:56:52

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '13:06'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:56:52

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '30 Sep 2020 13:06'	System	30 Sep 2020 19:56:52

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	30 Sep 2020 19:57:09



**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '13:30'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '30 Sep 2020 13:30'	System	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:57:09

**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered empty.	System	30 Sep 2020 19:57:09

US3602008

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:04:07



**US3602008**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '1'	System	30 Sep 2020 20:04:07

**US3602008**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:37:35

US3602008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	17 Nov 2020 22:33:09
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	28 Oct 2020 14:37:35
User entered '7 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 14:37:35

**US3602008**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:37:35

US3602008

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Subject had an A.E and was feeling anxious. SUBJECT DID NOT want to RECEIVE INVESTIGATIONAL AGENT DOSE 2 but still is continuing on with study.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:00:44
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 14:37:35

**US3602008**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:38:19

**US3602008**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	28 Oct 2020 14:38:19

**US3602008**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:39:01



US3602008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	17 Nov 2020 22:33:09
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	28 Oct 2020 14:39:01
User entered '14 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 14:39:01

US3602008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:02:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Oct 2020 14:39:01

US3602008

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'SUBJECT HAD AN A.E AND WAS FEELING ANXIOUS. SUBJECT DID NOT WANT TO RECEIVE INVESTIGATIONAL AGENT DOSE 2 BUT STILL IS CONTINUING ON WITH STUDY.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:01:05
User entered 'Subject did not receive investigational agent Dose 2.	(b) (4), (b) (6)	06 Nov 2020 18:02:27
Called at 6:54pm and 7:40pm without success. Call back number and message was let on his voicemail.' reason for change: New Information		
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 14:39:01

**US3602008**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:39:07

**US3602008**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	28 Oct 2020 14:39:07

**US3602008**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:03:06

US3602008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	(b) (4) System	17 Nov 2020 22:33:09
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	06 Nov 2020 18:03:06
User entered '21 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 18:03:06

**US3602008**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:03:06



US3602008

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'SUBJECT HAD AN A.E AND WAS FEELING ANXIOUS. SUBJECT DID NOT WANT TO RECEIVE INVESTIGATIONAL AGENT DOSE 2 BUT STILL IS CONTINUING ON WITH STUDY.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:01:24
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 18:03:06

**US3602008**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:03:38

**US3602008**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	06 Nov 2020 18:03:38

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:42:39

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:42:39

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:42:39

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'VISIT3'	System	19 Nov 2020 18:42:39

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06



US3602008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '11:00'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '19 Nov 2020 11:00'	System	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '68'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'bpm'	System	19 Nov 2020 18:44:06



**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'breaths/min'	System	19 Nov 2020 18:44:06

US3602008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '130'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '84'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:06

US3602008

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'mmHg'	System	19 Nov 2020 18:44:06

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56



**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:20

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:54:00
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:20

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:34

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:34

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered '11:00'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:34

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered '19 Nov 2020 11:00'	System	19 Nov 2020 18:44:34

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	15 Feb 2021 20:55:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:50

**US3602008**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	19 Nov 2020 18:44:50



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 64'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 20:28:57

US3602008

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:58:24

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 71'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:58:24**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:53
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 20:28:57



**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered 'Day 78'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-11-18T12:01:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c8f3b2f9-2de8-43c3-baa5-21577a4ff025'	System	18 Nov 2020 17:01:23
User entered 'No (N)'	System	18 Nov 2020 17:01:23
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-11-18T12:01:04', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c8f3b2f9-2de8-43c3-baa5-21577a4ff025'	System	18 Nov 2020 17:01:23
User entered 'No (N)'	System	18 Nov 2020 17:01:23
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-11-18T12:01:11', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c8f3b2f9-2de8-43c3-baa5-21577a4ff025'	System	18 Nov 2020 17:01:23
User entered '18 Nov 2020 12:01:11'	System	18 Nov 2020 17:01:23
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 01:04:15
DataPoint Activated.	System	17 Nov 2020 22:33:09
DataPoint Inactivated.	System	13 Oct 2020 16:11:55
Data entry locked.	System	02 Sep 2020 20:28:57
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 20:28:57

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-11-30T08:21:22', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b8040c37-f0cb-4693-84c6-886d1c046418' User entered 'No (N)'	System	30 Nov 2020 13:21:34

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-11-30T08:21:26', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b8040c37-f0cb-4693-84c6-886d1c046418' User entered 'No (N)'	System	30 Nov 2020 13:21:34

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-11-30T08:21:31', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b8040c37-f0cb-4693-84c6-886d1c046418' User entered '30 Nov 2020 08:21:31'	System	30 Nov 2020 13:21:34
	System	30 Nov 2020 13:21:34

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-04T00:12:36', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '144f446c-7cae-42b7-a9b7-4cee8a688026' User entered 'No (N)'	System	04 Dec 2020 05:12:48
	System	04 Dec 2020 05:12:48

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-04T00:12:41', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '144f446c-7cae-42b7-a9b7-4cee8a688026'	System	04 Dec 2020 05:12:48
User entered 'No (N)'	System	04 Dec 2020 05:12:48

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-04T00:12:46', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '144f446c-7cae-42b7-a9b7-4cee8a688026' User entered '04 Dec 2020 00:12:46'	System	04 Dec 2020 05:12:48
	System	04 Dec 2020 05:12:48

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-13T17:09:19', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '6e3f946b-9a90-49dc-81b6-47d252735356'	System	13 Dec 2020 22:09:32
User entered 'No (N)'	System	13 Dec 2020 22:09:32

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-13T17:09:23', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '6e3f946b-9a90-49dc-81b6-47d252735356'	System	13 Dec 2020 22:09:32
User entered 'No (N)'	System	13 Dec 2020 22:09:32



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-13T17:09:28', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '6e3f946b-9a90-49dc-81b6-47d252735356' User entered '13 Dec 2020 17:09:28'	System	13 Dec 2020 22:09:32
	System	13 Dec 2020 22:09:32

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-18T06:49:21', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b525e10f-6aaf-4818-a8e6-79b501d1eb53'	System	18 Dec 2020 11:49:36
User entered 'No (N)'	System	18 Dec 2020 11:49:36

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-18T06:49:25', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b525e10f-6aaf-4818-a8e6-79b501d1eb53'	System	18 Dec 2020 11:49:36
User entered 'No (N)'	System	18 Dec 2020 11:49:36

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-18T06:49:30', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'b525e10f-6aaf-4818-a8e6-79b501d1eb53' User entered '18 Dec 2020 06:49:30'	System	18 Dec 2020 11:49:36
	System	18 Dec 2020 11:49:36

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-26T14:11:05', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c853e5bf-097f-4dfc-b79f-a3c3090b1a3b' User entered 'No (N)'	System	26 Dec 2020 19:11:15
	System	26 Dec 2020 19:11:15

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-26T14:11:09', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c853e5bf-097f-4dfc-b79f-a3c3090b1a3b' User entered 'No (N)'	System	26 Dec 2020 19:11:15
	System	26 Dec 2020 19:11:15

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2020-12-26T14:11:13', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'c853e5bf-097f-4dfc-b79f-a3c3090b1a3b' User entered '26 Dec 2020 14:11:13'	System	26 Dec 2020 19:11:15
	System	26 Dec 2020 19:11:15

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-03T22:17:18', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'fa1f46a5-dabc-4b83-b2bd-7c2fd5d17624'	System	04 Jan 2021 03:17:29
User entered 'No (N)'	System	04 Jan 2021 03:17:29

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-03T22:17:22', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'fa1f46a5-dabc-4b83-b2bd-7c2fd5d17624'	System	04 Jan 2021 03:17:29
User entered 'No (N)'	System	04 Jan 2021 03:17:29

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-03T22:17:26', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'fa1f46a5-dabc-4b83-b2bd-7c2fd5d17624'	System	04 Jan 2021 03:17:29
User entered '03 Jan 2021 22:17:26'	System	04 Jan 2021 03:17:29

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-08T08:25:53', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '01333d4b-a482-497b-8158-f0e2eb25941a' User entered 'No (N)'	System	08 Jan 2021 13:26:05
	System	08 Jan 2021 13:26:05

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-08T08:25:57', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '01333d4b-a482-497b-8158-f0e2eb25941a' User entered 'No (N)'	System	08 Jan 2021 13:26:05
	System	08 Jan 2021 13:26:05



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-08T08:26:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '01333d4b-a482-497b-8158-f0e2eb25941a' User entered '08 Jan 2021 08:26:00'	System	08 Jan 2021 13:26:05
	System	08 Jan 2021 13:26:05

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-15T07:59:08', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '74da2b60-3bd1-49fe-9af0-fa9d2d6d0336'	System	19 Jan 2021 15:14:00
User entered 'No (N)'	System	19 Jan 2021 15:14:00

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-15T07:59:12', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '74da2b60-3bd1-49fe-9af0-fa9d2d6d0336'	System	19 Jan 2021 15:14:00
User entered 'No (N)'	System	19 Jan 2021 15:14:00

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-15T07:59:16', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '74da2b60-3bd1-49fe-9af0-fa9d2d6d0336'	System	19 Jan 2021 15:14:00
User entered '15 Jan 2021 07:59:16'	System	19 Jan 2021 15:14:00

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-22T09:24:40', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7e78ecce-16e8-47bc-8da1-58210ed6c933'	System	22 Jan 2021 14:24:49
User entered 'No (N)'	System	22 Jan 2021 14:24:49

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-22T09:24:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7e78ecce-16e8-47bc-8da1-58210ed6c933'	System	22 Jan 2021 14:24:49
User entered 'No (N)'	System	22 Jan 2021 14:24:49

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-22T09:24:47', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7e78ecce-16e8-47bc-8da1-58210ed6c933' User entered '22 Jan 2021 09:24:47'	System	22 Jan 2021 14:24:49
	System	22 Jan 2021 14:24:49

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-29T07:44:10', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '25996545-ff19-468a-912d-fd5b61a6bc90'	System	31 Jan 2021 20:03:52
User entered 'No (N)'	System	31 Jan 2021 20:03:52

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-29T07:44:13', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '25996545-ff19-468a-912d-fd5b61a6bc90'	System	31 Jan 2021 20:03:52
User entered 'No (N)'	System	31 Jan 2021 20:03:52

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-01-29T07:44:18', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '25996545-ff19-468a-912d-fd5b61a6bc90'	System	31 Jan 2021 20:03:52
User entered '29 Jan 2021 07:44:18'	System	31 Jan 2021 20:03:52

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-06T13:19:39', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '003b6943-78ec-4d63-865b-595e6feb6172'	System	06 Feb 2021 18:19:50
User entered 'No (N)'	System	06 Feb 2021 18:19:50

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-06T13:19:44', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '003b6943-78ec-4d63-865b-595e6feb6172'	System	06 Feb 2021 18:19:50
User entered 'No (N)'	System	06 Feb 2021 18:19:50



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-06T13:19:48', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '003b6943-78ec-4d63-865b-595e6feb6172' User entered '06 Feb 2021 13:19:48'	System	06 Feb 2021 18:19:50
	System	06 Feb 2021 18:19:50

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-19T09:25:12', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '601838fd-f824-47f2-a12e-a343e2850513' User entered 'No (N)'	System	19 Feb 2021 14:25:23
	System	19 Feb 2021 14:25:23



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-19T09:25:16', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '601838fd-f824-47f2-a12e-a343e2850513'	System	19 Feb 2021 14:25:23
User entered 'No (N)'	System	19 Feb 2021 14:25:23

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-19T09:25:20', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '601838fd-f824-47f2-a12e-a343e2850513' User entered '19 Feb 2021 09:25:20'	System	19 Feb 2021 14:25:23
	System	19 Feb 2021 14:25:23

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-26T08:46:15-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7031366e-521e-46c8-9500-0e6be6465d1e' User entered 'No (N)'	System	26 Feb 2021 13:46:25
	System	26 Feb 2021 13:46:25

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-26T08:46:19-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7031366e-521e-46c8-9500-0e6be6465d1e' User entered 'No (N)'	System	26 Feb 2021 13:46:25
	System	26 Feb 2021 13:46:25

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-26T08:46:23-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '7031366e-521e-46c8-9500-0e6be6465d1e' User entered '26 Feb 2021 13:46:23'	System	26 Feb 2021 13:46:25
	System	26 Feb 2021 13:46:25



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-09T13:21:58-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '6e3571e7-f3cf-44e0-8609-93ee484e3103'	System	09 Mar 2021 18:22:06
User entered 'No (N)'	System	09 Mar 2021 18:22:06

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-09T13:22:01-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '6e3571e7-f3cf-44e0-8609-93ee484e3103'	System	09 Mar 2021 18:22:06
User entered 'No (N)'	System	09 Mar 2021 18:22:06

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-09T13:22:04-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '6e3571e7-f3cf-44e0-8609-93ee484e3103'	System	09 Mar 2021 18:22:06
User entered '09 Mar 2021 13:22:04'	System	09 Mar 2021 18:22:06

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-15T15:21:35-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '73c005d5-b56e-4809-8aad-fb43ab204c54'	System	15 Mar 2021 19:21:45
User entered 'No (N)'	System	15 Mar 2021 19:21:45

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-15T15:21:38-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '73c005d5-b56e-4809-8aad-fb43ab204c54'	System	15 Mar 2021 19:21:45
User entered 'No (N)'	System	15 Mar 2021 19:21:45

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-15T15:21:43-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '73c005d5-b56e-4809-8aad-fb43ab204c54'	System	15 Mar 2021 19:21:45
User entered '15 Mar 2021 15:21:43'	System	15 Mar 2021 19:21:45

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-19T10:03:17-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3d9e0191-fd68-43af-9d13-23f091217929'	System	19 Mar 2021 14:03:26
User entered 'No (N)'	System	19 Mar 2021 14:03:26



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-19T10:03:20-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3d9e0191-fd68-43af-9d13-23f091217929'	System	19 Mar 2021 14:03:26
User entered 'No (N)'	System	19 Mar 2021 14:03:26

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-19T10:03:23-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '3d9e0191-fd68-43af-9d13-23f091217929' User entered '19 Mar 2021 10:03:23'	System	19 Mar 2021 14:03:26
	System	19 Mar 2021 14:03:26

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-26T11:45:41-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'a828fe08-5d96-4e09-af15-cad923ad313a'	System	30 Mar 2021 22:43:49
User entered 'No (N)'	System	30 Mar 2021 22:43:49

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-26T11:45:44-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'a828fe08-5d96-4e09-af15-cad923ad313a'	System	30 Mar 2021 22:43:49
User entered 'No (N)'	System	30 Mar 2021 22:43:49

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-03-26T11:45:47-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'a828fe08-5d96-4e09-af15-cad923ad313a' User entered '26 Mar 2021 11:45:47'	System	30 Mar 2021 22:43:49
	System	30 Mar 2021 22:43:49



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-04-02T08:55:38-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '44ec1f6c-68fd-463d-8db8-c19ab58836da' User entered 'No (N)'	System	02 Apr 2021 12:55:48

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

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?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-04-02T08:55:41-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '44ec1f6c-68fd-463d-8db8-c19ab58836da' User entered 'No (N)'	System	02 Apr 2021 12:55:48

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-04-02T08:55:45-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: '44ec1f6c-68fd-463d-8db8-c19ab58836da'	System	02 Apr 2021 12:55:48
User entered '02 Apr 2021 08:55:45'	System	02 Apr 2021 12:55:48

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-04-09T02:04:10-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cb1c9772-08be-4e07-932c-384db266dc3a'	System	09 Apr 2021 06:04:17
User entered 'No (N)'	System	09 Apr 2021 06:04:17

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[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?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-04-09T02:04:12-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cb1c9772-08be-4e07-932c-384db266dc3a'	System	09 Apr 2021 06:04:17
User entered 'No (N)'	System	09 Apr 2021 06:04:17

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-04-09T02:04:16-04:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'cb1c9772-08be-4e07-932c-384db266dc3a'	System	09 Apr 2021 06:04:17
User entered '09 Apr 2021 02:04:16'	System	09 Apr 2021 06:04:17

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:50:53



**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:50:53

**US3602008**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:58:24**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:53
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:50:53

US3602008

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:58:24

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-28T14:16:52-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'e84ac767-b65d-4af0-90f5-83af2786f0e7'	System	28 Feb 2021 19:16:58
User entered 'No (N)'	System	28 Feb 2021 19:16:58

**US3602008**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (19630C6D-3A45-41B6-BF70-921B34C4EC8E)', Time: '2021-02-28T14:16:56-05:00', User OID: 'PatientReportedOutcome (US3602008)', ODM File OID: 'e84ac767-b65d-4af0-90f5-83af2786f0e7' User entered '28 Feb 2021 14:16:56'	System	28 Feb 2021 19:16:58
	System	28 Feb 2021 19:16:58

**US3602008**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 22:04:16

**US3602008**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '25 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 22:04:16



**US3602008**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 22:04:16

**US3602008**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 22:04:16

**US3602008**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 22:04:23

**US3602008**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:19:56
User entered 'I'	System	04 Dec 2020 22:04:23

**US3602008**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 03:55:27

**US3602008**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 03:55:27

**US3602008**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 03:55:27

**US3602008**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 03:55:27



**US3602008**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 03:55:33

**US3602008**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered '1'	System	12 Jan 2021 03:55:33

**US3602008**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:58:57

**US3602008**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:58:57

**US3602008**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:58:57

US3602008

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:58:24

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 22:40:02
User entered 'Missed safety call due to lack of clarification of EUA protocol for combining safety calls from Part A and Part B.' reason for change: New Information	(b) (4), (b) (6)	23 Mar 2021 22:40:02
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:58:57

**US3602008**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:59:05

**US3602008**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered 'I'	System	04 Feb 2021 15:59:05



**US3602008**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:20:11

**US3602008**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '3 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:20:11

**US3602008**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:20:11

**US3602008**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:20:11

**US3602008**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:20:18

**US3602008**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered '1'	System	09 Mar 2021 02:20:18

US3602008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
User closed query 'Per Clinical: The site entered that the OL D57 and D209 visits were combined; however this was a mistake. OL D57 was completed 3/4/21 and D209 was completed 4/9/21 and the site needs all pages for D209 unlocked in order to enter the correct data. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 22:20:08
Query 'Per Clinical: The site entered that the OL D57 and D209 visits were combined; however this was a mistake. OL D57 was completed 3/4/21 and D209 was completed 4/9/21 and the site needs all pages for D209 unlocked in order to enter the correct data. ' answered with 'Data updated for visit per source. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 14:01:02
User opened query 'Per Clinical: The site entered that the OL D57 and D209 visits were combined; however this was a mistake. OL D57 was completed 3/4/21 and D209 was completed 4/9/21 and the site needs all pages for D209 unlocked in order to enter the correct data. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 10:34:13
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:38
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 02:23:42

US3602008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:57:48
User entered '9 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:57:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:38
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '4 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 02:23:42



US3602008

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:58:24

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:38
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Mar 2021 02:23:42

**US3602008**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:38
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered 'VISIT4'	System	09 Mar 2021 02:23:42

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 20:15:12
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:59:36
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	29 Apr 2021 13:59:36
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User entered '9 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:57:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User entered '12:35' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:59:36
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '12:25'	(b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
User entered '9 Apr 2021 12:35'	System	29 Apr 2021 13:59:36
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered '4 Mar 2021 12:25'	System	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User entered '97.8' F reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:59:36
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '97' F	(b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered 'Other (Other)'	(b) (4), (b) (6)	30 Mar 2021 16:49:15



US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered 'Temporal/Forehead scanner was used'	(b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User entered '63' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:59:36
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '74'	(b) (4), (b) (6)	30 Mar 2021 16:49:15

**US3602008**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered 'bpm'	System	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered 'breaths/min'	System	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User entered '147' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:59:36
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '127'	(b) (4), (b) (6)	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered 'mmHg'	System	30 Mar 2021 16:49:15

US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 13:59:36
User entered '87' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 13:59:36
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:58
	(b) (4)	
User entered '79'	(b) (4), (b) (6)	30 Mar 2021 16:49:15



US3602008

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:58:24

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered 'mmHg'	System	30 Mar 2021 16:49:15

**US3602008**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20

**US3602008**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:44
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20

US3602008

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:50
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 02:23:51

US3602008

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:58:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 20:15:12
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Apr 2021 14:00:06
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 14:00:06
User entered '9 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 14:00:06
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:57:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:50
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:23:51

US3602008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:56
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 02:24:13

US3602008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
Data hard locked.	(b) (4) (b) (4), (b) (6)	01 May 2021 20:15:12
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Apr 2021 14:00:32
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		29 Apr 2021 14:00:32
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 14:00:32
User entered '9 Apr 2021' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 14:00:32
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:57:48
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:56
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:24:13

US3602008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	02 May 2021 01:32:49
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 14:00:32
User entered '12:45' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 14:00:32
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:56
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
	(b) (4)	
User entered '12:30' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 02:25:21
User entered '12:25'	(b) (4), (b) (6)	09 Mar 2021 02:24:13



US3602008

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
User entered '9 Apr 2021 12:45'	System	29 Apr 2021 14:00:32
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:33:56
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered '4 Mar 2021 12:30'	System	09 Mar 2021 02:25:21
User entered '4 Mar 2021 12:25'	System	09 Mar 2021 02:24:13

US3602008

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:58:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:34:01
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 02:24:19

**US3602008**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:15:12
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 10:34:01
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:53:20
User entered '1'	System	09 Mar 2021 02:24:19

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:57:04

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:57:04

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:57:04

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 23:57:04

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:11



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:56:22
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:03:20

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: New Information	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:03:43
	(b) (4), (b) (6)	09 Mar 2021 01:56:22
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:03:20

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:11

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:58:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 08:57:32
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:56:22
User entered 'Not Administered (NA)' reason for change: New Information	(b) (4), (b) (6)	09 Mar 2021 01:56:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 08:57:32
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:11



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '1'	System	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'I'	System	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered empty.	System	07 Jan 2021 00:02:15
DataPoint set to visible.	System	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered empty.	System	07 Jan 2021 00:02:15
DataPoint set to visible.	System	06 Jan 2021 23:58:11



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '14:45'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '6 Jan 2021 14:45'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '73'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'bpm'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '18'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'breaths/min'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '102' reason for change: New Information	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:58
User entered '117'	(b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mmHg'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '68' reason for change: New Information	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:58
User entered '81'	(b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mmHg'	System	07 Jan 2021 00:02:15



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:58:24**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered empty.	System	07 Jan 2021 00:02:15
DataPoint set to visible.	System	06 Jan 2021 23:58:11

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Jan 2021 00:02:15

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:58:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '17:15'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '6 Jan 2021 17:15'	System	07 Jan 2021 00:02:15



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '73'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'bpm'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '18'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'breaths/min'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '141'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mmHg'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '71'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mmHg'	System	07 Jan 2021 00:02:15

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:03:28

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:03:28

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:00:26

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:00:26

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:00:26



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mRNA-1273'	System	07 Jan 2021 19:00:26
DataPoint set to visible.	System	06 Jan 2021 23:58:11

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:00:26

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '16:45'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:00:26

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '6 Jan 2021 16:45'	System	07 Jan 2021 19:00:26

US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:00:26

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'ONCE'	System	07 Jan 2021 19:00:26

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'INTRAMUSCULAR'	System	07 Jan 2021 19:00:26

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:06:49



US3602008

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:58:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:19:23
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' answered with 'Confirming the correct Immunogenicity Assessment sample date is 06Jan2021.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:15:35
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:39:10
User entered '6 Jan 2021'	(b) (4), (b) (6)	07 Jan 2021 00:06:49

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '15:25'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:06:49

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '6 Jan 2021 15:25'	System	07 Jan 2021 00:06:49

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:08:55

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:08:55

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '15:05'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:08:55

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:58:24**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '6 Jan 2021 15:05'	System	07 Jan 2021 00:08:55

**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 00:09:15



**US3602008**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'I'	System	07 Jan 2021 00:09:15

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:41:02

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:41:02

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:41:02

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:41:02

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:41:40

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'I'	System	14 Jan 2021 15:41:40

**US3602008**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '1'	System	14 Jan 2021 15:41:40
DataPoint set to visible.	System	14 Jan 2021 15:41:40



**US3602008**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:29:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:29:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:29:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'OLD29'	System	12 Feb 2021 22:29:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '14:36'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22



**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered '4 Feb 2021 14:36'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '76'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'bpm'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'breaths/min'	System	15 Feb 2021 20:07:22



**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '118'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'mmHg'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '86'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'mmHg'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '16:30'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22



**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered '4 Feb 2021 16:30'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '74'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'bpm'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'breaths/min'	System	15 Feb 2021 20:07:22



**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '129'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'mmHg'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '77'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'mmHg'	System	15 Feb 2021 20:07:22

**US3602008**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:29:51

**US3602008**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:29:51

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:30:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:30:17



**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:30:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'mRNA-1273'	System	12 Feb 2021 22:30:17
DataPoint set to visible.	System	14 Jan 2021 15:41:40

US3602008

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:30:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '16:00'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:30:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered '4 Feb 2021 16:00'	System	12 Feb 2021 22:30:17

US3602008

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:58:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:30:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'ONCE'	System	12 Feb 2021 22:30:17

**US3602008**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:58:24**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 22:30:17



**US3602008**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:35:27

**US3602008**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'I'	System	12 Feb 2021 22:35:27

**US3602008**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:35:43

**US3602008**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:35:43

**US3602008**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:35:43

**US3602008**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:58:24**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:35:43

**US3602008**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 22:35:52

**US3602008**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:58:24**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'I'	System	12 Feb 2021 22:35:52



**US3602008**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:24:38

**US3602008**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:24:38

**US3602008**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:24:38

**US3602008**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:58:24**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered 'OLD57'	System	09 Mar 2021 02:24:38

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '12:25'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered '4 Mar 2021 12:25'	System	09 Mar 2021 02:26:19



**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '97' F	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '74'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'bpm'	System	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '18'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'breaths/min'	System	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '127'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19



**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mmHg'	System	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '79'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10
User entered 'mmHg'	System	09 Mar 2021 02:26:19

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10

**US3602008**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:58:24**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:48:10

**US3602008**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:24:46

**US3602008**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:24:46

**US3602008**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:25:04



**US3602008**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:25:04

**US3602008**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User entered '12:30'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 02:25:04

**US3602008**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:58:24**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:47:59
User entered '4 Mar 2021 12:30'	System	09 Mar 2021 02:25:04

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:58:24**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:58:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:21:11

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia aggravated - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 07:44:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:44:16
User closed query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:35:54
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of ARTHRALGIAS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure that grade is greater than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:35:52
Data point term sent to Coder	System	20 Nov 2020 18:07:35
Query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Updated entry per provider notes in EMR. EMR states located is "bilateral shoulder and bil hand".' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:07:10
User entered 'WORSENING JOINT ACHES OR PAIN located in bilateral shoulder and hands' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Nov 2020 18:07:04
Data point term sent to Coder	System	20 Nov 2020 18:04:32

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please confirm if this AE is a worsening of ARTHRALGIAS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure that grade is greater than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' answered with 'Entry updated per new notes in EMR' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	20 Nov 2020 18:04:12
	(b) (4), (b) (6)	20 Nov 2020 18:03:34
User entered 'Worsening JOINT ACHES OR PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 18:03:34
User opened query 'Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:48:39
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of ARTHRALGIAS noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure that grade is greater than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:48:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:17:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:17:16
Data point term sent to Coder	System	08 Oct 2020 17:32:10
User entered 'Joint aches or pain'	(b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Oct 2020 10:43:40
User closed query 'Per CDM re-query: Response noted, If outcome is 'Unknown'. Please confirm if the AE has been resolved or subject lost to follow-up and update "End Date accordingly or clarify why outcome is 'Unknown. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 04:52:31
Query 'Per CDM re-query: Response noted, If outcome is 'Unknown'. Please confirm if the AE has been resolved or subject lost to follow-up and update "End Date accordingly or clarify why outcome is 'Unknown. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 19:30:38
User opened query 'Per CDM re-query: Response noted, If outcome is 'Unknown'. Please confirm if the AE has been resolved or subject lost to follow-up and update "End Date accordingly or clarify why outcome is 'Unknown. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:08:33
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Outcome is unknown per EMR. End date not stated in EMR. See narrative section below for more info' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 17:35:24
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:34:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 17:34:11
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 17:34:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 17:32:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 17:32:42
User entered 'UN Sep 2020' (non-conformant).	(b) (4), (b) (6)	08 Oct 2020 17:32:42

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 17:32:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:32:30
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Oct 2020 17:32:30
User entered 'UN 2020' (non-conformant).	(b) (4), (b) (6)	08 Oct 2020 17:32:30
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:32:06
User entered '15 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	20 Nov 2020 18:03:34
reason for change: New Information	(b) (4), (b) (6)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per CDM: it appears more than 1 record is recorded with IP Withdrawn. Please review and reconcile as only record the primary cause leading to IP Withdrawn as IP Withdrawn ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 05:16:28
Query 'Per CDM: it appears more than 1 record is recorded with IP Withdrawn. Please review and reconcile as only record the primary cause leading to IP Withdrawn as IP Withdrawn ' answered with 'Updated per query' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:48:21
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 13:48:18
User opened query 'Per CDM: it appears more than 1 record is recorded with IP Withdrawn. Please review and reconcile as only record the primary cause leading to IP Withdrawn as IP Withdrawn ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:38:09
User closed query 'Per CDM: Response provided as 'updated' however, not data has been updated yet. Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:26:59
Query 'Per CDM: Response provided as 'updated' however, not data has been updated yet. Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Action taken with IP is Withdrawn due to an A.E (Which is recorded in Medidata) anxiety due the side effects of the first IP' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:41:58
User opened query 'Per CDM: Response provided as 'updated' however, not data has been updated yet. Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:51:28



US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Re-query: Response provided as 'updated' however, not data has been updated yet. Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' canceled (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:51:09
User opened query 'Per CDM: Re-query: Response provided as 'updated' however, not data has been updated yet. Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:50:53
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:49:40
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 16:13:22
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	13 Oct 2020 16:11:34
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:25:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Added partial con med info, awaiting more info from provider' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:08:31
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:48:50
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 19:30:25
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

US3602008

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:58:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Onset date: D# 8 post vaccine Severity: Mild Action taken: took celbrex PRN once daily initially then every other day during Week 3 · Resolution: Resolution of shoulder pain by week 3. Improvement in hand stiffness by week 4. Outcome: residual mild hand stiffness ·any meds taken : celebrex. ·Any medical attn for the AE: no Left message to have pt return call	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:32:06

1. I am aware that he would like not to proceed with the second shot : I wanted to confirm the same
2. Wanted to find out hiw his s/s were today ( arthralgias)
3. Wanted to see if the patient would like to participate in the rest of the follow up with the remainder of the blood drwas and safety call follow up over the next 24 months

Asked him to call back the COVID vaccine hot line'

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 17:32:06



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Oct 2020 17:32:06

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55

US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Vaccination related complications, PT: Immunisation anxiety related reaction, LLT: Immunization anxiety related reaction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 21:32:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 21:32:50
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:06:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Neurological and psychiatric procedural complications, PT: Procedural anxiety, LLT: Procedural anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:24:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 21:24:17
Data point term sent to Coder	System	14 Oct 2020 20:31:16
User entered 'Anxiety due the side effects of the first IP'	(b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User entered empty.	System	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 03:24:28
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Outcome is unknown per EMR' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 16:47:08
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 16:45:33
User entered '30 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 20:31:15

US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	14 Oct 2020 20:31:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 20:31:36
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	14 Oct 2020 20:31:15
User entered '13:30'	(b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User entered empty.	System	14 Oct 2020 20:31:36
User entered '30 Sep 2020 13:30'	System	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15



**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however on Dosing discontinuation form "Primary reason for Dosing Discontinuation" field has not been updated. Please reconcile and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 05:59:16
Query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however on Dosing discontinuation form "Primary reason for Dosing Discontinuation" field has not been updated. Please reconcile and update as appropriate.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 18:55:03
User opened query 'Per CDM: Action Taken with Investigational Product is Withdrawn, however on Dosing discontinuation form "Primary reason for Dosing Discontinuation" field has not been updated. Please reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 07:17:04
User closed query 'Per CDM: Response provided as 'Per EMR: "PT DID NOT WANT TO TAKE THE NEXT .... REOCCUR AGAIN" however, Primary reason for Dosing Discontinuation is NOT AE. Please consider to update the primary reason as 'AE' based on provided response or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:25:24
Query 'Per CDM: Response provided as 'Per EMR: "PT DID NOT WANT TO TAKE THE NEXT .... REOCCUR AGAIN" however, Primary reason for Dosing Discontinuation is NOT AE. Please consider to update the primary reason as 'AE' based on provided response or else clarify. Thank you. ' answered with 'Primary reason is : anxiety due the side effects of the first IP per EMR (this was documented as an A.E' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:43:37

US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Response provided as 'Per EMR: "PT DID NOT WANT TO TAKE THE NEXT .... REOCCUR AGAIN" however, Primary reason for Dosing Discontinuation is NOT AE. Please consider to update the primary reason as 'AE' based on provided response or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:25:13
Query 'Per CDM: Response provided as 'Per EMR: "PT DID NOT WANT TO TAKE THE NEXT .... REOCCUR AGAIN" however, Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please consider to update the primary reason as 'AE' based on response or else clarify. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:24:08
User opened query 'Per CDM: Response provided as 'Per EMR: "PT DID NOT WANT TO TAKE THE NEXT .... REOCCUR AGAIN" however, Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please consider to update the primary reason as 'AE' based on response or else clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 12:59:30
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 12:59:20
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Per EMR: "PT DID NOT WANT TO TAKE THE NEXT ip GIVEN THE WORRY THAT THE ARTHRALGIAS MAY REOCCUR AGAIN"' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 20:31:51
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	14 Oct 2020 20:31:15
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15



US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
User closed query 'Per CDM: Site response indicates that the outcome is unknown; yet there is an end date provided and, per data in EDC, the participant is still in the study. Please review and reconcile data. Otherwise, please clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:01:07
Query 'Per CDM: Site response indicates that the outcome is unknown; yet there is an end date provided and, per data in EDC, the participant is still in the study. Please review and reconcile data. Otherwise, please clarify. ' answered with 'Outcome updated in source on 3/26. Entry updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:34:40
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 15:33:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	26 Mar 2021 15:33:42
User opened query 'Per CDM: Site response indicates that the outcome is unknown; yet there is an end date provided and, per data in EDC, the participant is still in the study. Please review and reconcile data. Otherwise, please clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:55:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per CDM: Response noted. However, This is not the required response. Kindly select the outcome of the AE from provided drop down or provide clarification. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 03:21:40
Query 'Per CDM: Response noted. However, This is not the required response. Kindly select the outcome of the AE from provided drop down or provide clarification. Thank you.' answered with ""PT DID NOT WANT TO TAKE THE NEXT ip GIVEN THE WORRY THAT THE ARTHRALGIAS MAY REOCCUR AGAIN" so subject withdrew. Outcome is Unknown per EMR' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:46:03

US3602008

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:58:24

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:45:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 10:16:20
User opened query 'Per CDM: Response noted. However, This is not the required response. Kindly select the outcome of the AE from provided drop down or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:16:18
Query 'Data is required. Please complete.' answered with 'No info provided in EMR' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 20:32:03
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 20:31:15
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User entered '0'	System	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55
User entered '0'	System	14 Oct 2020 20:31:15

**US3602008**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:00:55

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:58:24

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:58:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:13:20



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 07:03:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:03:11
Data point term sent to Coder	System	06 Nov 2020 18:05:20
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 18:04:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:11:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:11:48
Data point term sent to Coder	System	28 Oct 2020 16:51:38
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 16:51:27

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 08:30:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 08:30:48
Data point term sent to Coder	System	04 Sep 2020 16:18:29
User entered 'Janumet'	(b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Diabetes Mellitus' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:04:54
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:29:25
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:51:33
User entered 'FOR BLOOD SUGAR- DM' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:51:27
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:43:49
User entered 'For blood sugar'	(b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '1000/50'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:58:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55

US3602008

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:17:55



**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:17:55

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:17:55

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Nov 2020 07:26:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:26:15
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Nov 2020 18:05:20 06 Nov 2020 18:05:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:25:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 09:25:52
Data point term sent to Coder User entered 'Ramapril'	System (b) (4), (b) (6)	04 Sep 2020 16:21:40 04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per CDM re-query: Response noted. Please update the corresponding indication on Medical History / AE form. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 03:14:02
Query 'Per CDM re-query: Response noted. Please update the corresponding indication on Medical History / AE form. Thank you.' answered with 'HTN and HL added to Medical History tab per EMR' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 20:35:10
User opened query 'Per CDM re-query: Response noted. Please update the corresponding indication on Medical History / AE form. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:09:10
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:09:10
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:05:25
User entered 'for Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:05:15
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:43:58
User entered 'Not indicated'	(b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '1.25'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:58:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49



**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:20:49

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:20:49

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: ROSUVASTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 18:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 18:07:19
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	06 Nov 2020 18:06:22 06 Nov 2020 18:05:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: ROSUVASTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:37:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:37:53
Data point term sent to Coder User entered 'Rosuvastin'	System (b) (4), (b) (6)	04 Sep 2020 16:36:06 04 Sep 2020 16:35:20

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:17:32
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:05:49
User entered 'for Hyperlipidemia' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 18:05:44
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:44:14
User entered 'Not indicated'	(b) (4), (b) (6)	04 Sep 2020 16:35:20



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 04:21:10
Query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:55:17
User entered '20' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:55:08
User opened query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 08:44:23
User entered '20 mg'	(b) (4), (b) (6)	04 Sep 2020 16:35:20

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:58:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

US3602008

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20



**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:35:20

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:35:20

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B 12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Sep 2020 08:56:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 08:56:48
Data point term sent to Coder	System	04 Sep 2020 16:40:18
User entered 'Vitamin B 12'	(b) (4), (b) (6)	04 Sep 2020 16:39:43



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:08:49
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Nutritional needs/dietary supplement'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'unk'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:58:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:39:43

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:39:43



**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:39:43

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 16:45:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:45:47
Data point term sent to Coder	System	04 Sep 2020 16:44:28
User entered 'Vitamin D3'	(b) (4), (b) (6)	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:09:21
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Nutritional needs/dietary supplement'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '1000'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:58:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:40



**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:43:40

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:43:40

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 00:42:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	28 Jan 2021 00:42:09
Data point term sent to Coder	System	27 Jan 2021 18:05:11
Coding entries removed.	(b) (4), (b) (6)	27 Jan 2021 18:04:32
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:37:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	24 Nov 2020 06:37:04
Data point term sent to Coder	System	23 Nov 2020 13:56:06
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 13:55:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 08:08:02

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	18 Nov 2020 08:08:02
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	17 Nov 2020 16:07:45
User entered 'Celbrex'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 02:46:19
Query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	27 Jan 2021 18:04:48
' answered with 'Indication updated to match A.E recorded.' (Site from DM).		
User entered 'TO TREAT A.E- WORSENING JOINT ACHES OR PAIN LOCATED IN BILATERAL SHOULDER AND HANDS REPORTED ON DAY 21 ON 9/23' reason for change: Per Query Resolution	(b) (4), (b) (6)	27 Jan 2021 18:04:32
User opened query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:19:25
User entered 'To treat A.E- Joint aches or pain/ Arthralgias reported on Day 21 on 9/23'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '200' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered 'unknown'	(b) (4), (b) (6)	17 Nov 2020 16:07:31



US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'mg (mg)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered 'unknown'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'other (OTHER)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'once daily prn, in pm' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered 'Other (OTHER)'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered 'unknown'	(b) (4), (b) (6)	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '23 Sep 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '0' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 16:07:31



**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered '30 Sep 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:55:56
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	17 Nov 2020 16:07:49
User entered 'un UNK 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Nov 2020 16:07:49
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	17 Nov 2020 16:07:31
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:58:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User entered empty.	System	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User entered empty.	System	17 Nov 2020 16:07:31

**US3602008**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:58:24**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:11:44
User entered empty.	System	17 Nov 2020 16:07:31

US3602008

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:58:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:43:58

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:24

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 03:18:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per CDM Re-Query: response noted; however it appears Participant declined due to Adverse Event per Day 29 Exposure form and there are 2 adverse event records recorded as IP WITHDRAWN. once the primary cause leading to IP Discontinuation is determined, please complete this form as it is required due to adverse event.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 05:19:37
Query 'Per CDM Re-Query: response noted; however it appears Participant declined due to Adverse Event per Day 29 Exposure form and there are 2 adverse event records recorded as IP WITHDRAWN. once the primary cause leading to IP Discontinuation is determined, please complete this form as it is required due to adverse event.' answered with 'Updated date inserted due to dosing being discontinued ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:46:03
User entered '30 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 13:45:58
User opened query 'Per CDM Re-Query: response noted; however it appears Participant declined due to Adverse Event per Day 29 Exposure form and there are 2 adverse event records recorded as IP WITHDRAWN. once the primary cause leading to IP Discontinuation is determined, please complete this form as it is required due to adverse event.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:42:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Nov 2020 16:50:40
User closed query 'Per CDM: Response provided as 'Page completed in error' However, on Exposure form (V2 Day 29) the reason for study treatment not given is recorded as 'Participant declined due to Adverse Event'. Please confirm and consider to update Discontinuation form appropriately. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:27:48



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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:24

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Response provided as 'Page completed in error' However, on Exposure form (V2 Day 29) the reason for study treatment not given is recorded as 'Participant declined due to Adverse Event'. Please confirm and consider to update Discontinuation form appropriately. Thank you. ' answered with 'On V2D29 date 9/30/2020, subject #8 declined 2nd IP due to anxiety from A.E. This date was inserted per query.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:38:51
User entered '30 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 17:38:47
User opened query 'Per CDM: Response provided as 'Page completed in error' However, on Exposure form (V2 Day 29) the reason for study treatment not given is recorded as 'Participant declined due to Adverse Event'. Please confirm and consider to update Discontinuation form appropriately. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:38:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 06:25:47
Query 'Data is required. Please complete.' answered with 'Page completed in error' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 22:33:53
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 22:32:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:32:32
User closed query 'Per CDM: Date of dose discontinuation does not match any dose dates Treatment 1 Date;02SEP2020 and VISIT 2 DAY 29; 30SEP2020. Please update or else provide clarification. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:28:31
Query 'Per CDM: Date of dose discontinuation does not match any dose dates Treatment 1 Date;02SEP2020 and VISIT 2 DAY 29; 30SEP2020. Please update or else provide clarification. Thank you ' answered with 'Subject did not receive 2nd IP dose' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:48:14
User opened query 'Per CDM: Date of dose discontinuation does not match any dose dates Treatment 1 Date;02SEP2020 and VISIT 2 DAY 29; 30SEP2020. Please update or else provide clarification. Thank you ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:19:57

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:24

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 16:11:34

US3602008

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:24

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 03:18:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4)	17 Feb 2021 18:54:51
User closed query 'Per CDM: Kindly consider to complete the form and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:42:23
Query 'Per CDM: Kindly consider to complete the form and update accordingly. Thank you.' answered with 'Subject will NOT get 2nd IP dose but will continue with study. Page completed in error.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:51:11
User opened query 'Per CDM: Kindly consider to complete the form and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:29:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 06:25:51
Query 'Data is required. Please complete.' answered with 'Page completed in error' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 22:34:03
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 22:32:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:32:32
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	13 Oct 2020 16:11:34

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 20:56:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 03:18:07
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:59:07
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' answered with 'Updated per query resolution request.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 17:38:53
Signature has been broken.	(b) (4), (b) (6)	03 Mar 2021 17:38:37
User entered 'AE #2' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 17:38:37
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:07:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Per CDM:Kindly consider to keep only the AE log line number and consider removing the AETERM.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 09:39:49
Query 'Per CDM:Kindly consider to keep only the AE log line number and consider removing the AETERM.Thank you.' answered with 'Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:07:04
User entered 'A.E Log Line 2' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Feb 2021 15:06:17
User opened query 'Per CDM:Kindly consider to keep only the AE log line number and consider removing the AETERM.Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 06:03:08
User entered 'A.E Line #2: ANXIETY DUE THE SIDE EFFECTS OF THE FIRST IP' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Feb 2021 18:54:51

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:32:32
User entered 'DUE TO PREVIOUS AE and participant feeling anxious, PARTICIPANT DID NOT WANT TO CONTINUE WITH RECEIVING DOSE 2.' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 13:35:50
User entered 'Due to previous AE with first dose, participant did not want to continue with receiving dose 2.'	(b) (4), (b) (6)	13 Oct 2020 16:11:34

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:58:24

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 03:43:26
Query 'Data is required. Please complete.' answered with 'Page completed in error, subject did not withdraw, subject is still being followed in study. Not going to get 2nd IP' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 22:34:40
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 22:33:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:33:09
User entered '30 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 16:11:55

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:58:24

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 03:43:31
Query 'Data is required. Please complete.' answered with 'Page completed in error. Subject still in study but would not get 2nd IP' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 22:34:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 22:33:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 22:33:09
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	(b) (4), (b) (6)	13 Oct 2020 16:11:55

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:58:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:33:09
User entered 'DUE TO PREVIOUS AE AND PARTICIPANT FEELING ANXIOUS, PARTICIPANT DID NOT WANT TO CONTINUE WITH RECEIVING DOSE 2.' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 13:36:14
User entered 'Due to previous AE with first dose, participant did not want to continue with receiving dose 2.'	(b) (4), (b) (6)	13 Oct 2020 16:11:55



**US3602008**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:24**

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:11:55

**US3602008**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:24**

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:11:55

**US3602008**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:24**

**Date of death** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:11:55

**US3602008**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 11 Aug 2021 22:58:24**

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:48:42
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:06:53
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:11:55