

US3862175 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:33:42

All time stamps listed in this document are displayed in GMT

US3862175

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Participant ID

US3862175

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

US3862175

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Date of Birth (MMM yyyy)	(b) (6) 1968
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input checked="" type="radio"/> Male <input 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	False
Black	False
Asian	True
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) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 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) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

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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) 13 Feb 2021 00:58:22

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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) 13 Feb 2021 00:58:22

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Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Condition	CERVICAL RADICULOPATHY
Start date (dd MMM yyyy)	UN APR 2020
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)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:43
Height (xxx.x)	161.0 cm
Weight (xxx.x)	108.5 lb
BMI (xxx.x)	19.02634 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 00:58:22

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Date of assessment (dd MMM yyyy) 11 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 29 Mar 2021 15:58:00

Generated On: 12 Aug 2021 13:33:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	11 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:58:22

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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**

RESEARCH LAB PERSONNEL

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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) 13 Feb 2021 00:58:22

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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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113466

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) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

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) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

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)	11 SEP 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:43
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	072 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:57 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:57
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

Collection date and time (derived) \_\_\_\_\_



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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 15:25 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 15:25

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) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	14:37 (24 HR)
Collection date and time (derived)	11 SEP 2020 14:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	11 SEP 2020 14:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:48

Generated On: 12 Aug 2021 13:33:42

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: 12 Aug 2021 13:33:42

**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

97.9 °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

11 SEP 2020 15:50

PC Open Date & Time

11 SEP 2020 15:45

PC Close Date & Time

11 SEP 2020 18:15

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**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

98.1 °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

11 SEP 2020 20:52

PC Open Date & Time

11 SEP 2020 19:10

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**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

97.8 °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

12 SEP 2020 14:32

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

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**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

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

13 SEP 2020 13:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**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

97.9 °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

14 SEP 2020 20:04

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**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

97.8 °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

15 SEP 2020 22:22

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

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**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

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

16 SEP 2020 18:44

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**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

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

17 SEP 2020 21:30

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**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 ☒

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

11 SEP 2020 15:50

PC Open Date & Time

11 SEP 2020 15:45

PC Close Date & Time

11 SEP 2020 18:15

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**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

11 SEP 2020 20:53

PC Open Date & Time

11 SEP 2020 19:10

PC Close Date & Time

12 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**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

12 SEP 2020 14:31

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**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

13 SEP 2020 13:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**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)**

5

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 - **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

14 SEP 2020 20:06

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**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

15 SEP 2020 22:23

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**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

16 SEP 2020 18:45

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**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

17 SEP 2020 21:31

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**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 ☐

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 15:51
PC Open Date & Time	11 SEP 2020 15:45
PC Close Date & Time	11 SEP 2020 18:15

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**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 ☐

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:53
PC Open Date & Time	11 SEP 2020 19:10
PC Close Date & Time	12 SEP 2020 11:59



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

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: 12 Aug 2021 13:33:42

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 14:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

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 ☒

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 13:59
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

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 ☒

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:07
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

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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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 22:23
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

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 ☒

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:45
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

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 ☒

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:31
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:33:42

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 12:08
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

DAY 8

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 18 SEP 2020 17:50

PC Open Date and Time 18 SEP 2020 12:00

PC Close Date and Time 19 SEP 2020 11:59

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

DAY 9

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 19 SEP 2020 12:09

PC Open Date and Time 19 SEP 2020 12:00

PC Close Date and Time 20 SEP 2020 11:59

US3862175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3862175

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:58:21

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:21

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:58:21

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:21

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 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

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

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)	9 OCT 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:05
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

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	



US3862175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 22:32:58

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	9 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

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?

US3862175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	9 OCT 2020
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Collection time (00:00-23:59)	13:53 (24 HR)
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Collection date and time (derived)	9 OCT 2020 13:53
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US3862175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Collection date (dd MMM yyyy)			9 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	13:47	9 OCT 2020 13:47

US3862175

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:32:58

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments  
WOULD NOT RESPOND TO  
PHONE CALLS

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:32:58

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3862175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:21

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:22

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

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

Visit date (dd MMM yyyy)	6 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 NOV 2020
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 13:08
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
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3862175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Was the sample collected? Yes ☒ No ☐

Collection date (dd MMM yyyy) 6 NOV 2020

Collection time (00:00-23:59) 13:35 (24 HR)

Collection date and time (derived) 6 NOV 2020 13:35



US3862175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:58:49

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☒

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 NOV 2020 10:19:22

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

TIMEPOINT	DAY 75
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	24 NOV 2020 13:59:23
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 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	29 NOV 2020 13:50:40
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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	08 DEC 2020 09:54:57
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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	16 DEC 2020 16:10:59
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59



US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

21 DEC 2020 09:16:28

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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	28 DEC 2020 18:57:42
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

03 JAN 2021 21:10:22

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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	10 JAN 2021 14:46:48
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

20 JAN 2021 18:37:32

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

25 JAN 2021 18:59:51

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

<b>TIMEPOINT</b>	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 <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	02 FEB 2021 15:50:27
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

09 FEB 2021 12:00:33

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59



US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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	16 FEB 2021 15:47:11
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

<b>TIMEPOINT</b>	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 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	24 FEB 2021 00:19:31
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

01 MAR 2021 20:45:50

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <input type="radio"/> Yes <input checked="" 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 MAR 2021 10:53:49
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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	14 MAR 2021 15:10:40
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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	22 MAR 2021 12:02:12
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

30 MAR 2021 16:55:53

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

06 APR 2021 15:42:43

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59



US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

13 APR 2021 16:49:50

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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

20 APR 2021 12:39:51

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☒

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

27 APR 2021 09:39:57

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

<b>TIMEPOINT</b>	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 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 MAY 2021 12:05:53
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUL 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	25 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59
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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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°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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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°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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐  
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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	05 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 APR 2022 00:01

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14 APR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

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21 APR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐ 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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59



US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59



US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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="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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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°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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

**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°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 ☐

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3862175

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 <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"/>

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

13 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

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US3862175

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:33:42

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		01 MAR 2021 20:45:33

US3862175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:32:58

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:32:58

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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



US3862175

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

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

Visit date (dd MMM yyyy)	08 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Were vital signs assessed? Yes ☐  
No ☒

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 ☐  
Axillary ☐  
Other ☐

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 \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3862175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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



US3862175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 APR 2021

Collection time (00:00-23:59)

13:16 (24 HR)

Collection date and time (derived)

08 APR 2021 13:16

US3862175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3862175**

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

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

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*

**US3862175**

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

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862175

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:33:42

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"/>

**US3862175**

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

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

**Generated On: 12 Aug 2021 13:33:42**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3862175

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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

Visit date (dd MMM yyyy)	05 MAR 2021
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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
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US3862175

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Date of updated informed consent ( <i>dd MMM yyyy</i> )	05 MAR 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> )	05 MAR 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input 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	
Continuing with mRNA-1273	1



US3862175

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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

US3862175

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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)	5 MAR 2021
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 11:08
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 mmHg
Diastolic Blood Pressure units	MMHG

US3862175

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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)	5 MAR 2021
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 13:23
Temperature (xxx.x)	098.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3862175

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

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

US3862175

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

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	5 MAR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3862175

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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) 5 MAR 2021

What was the treatment time? (00:00-23:59) 12:52 (24 HR)

Treatment Date and Time (derived) 5 MAR 2021 12:52

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

US3862175

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 MAR 2021

Collection time (00:00-23:59)

11:18 (24 HR)

Collection date and time (derived)

5 MAR 2021 11:18

US3862175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	5 MAR 2021
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Collection time (00:00 - 23:59)	11:13
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Collection Date and Time (derived)	5 MAR 2021 11:13
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US3862175

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862175

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3862175

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

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

US3862175

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

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

Visit date (dd MMM yyyy)	08 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3862175

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Were vital signs assessed? Yes ☐  
No ☒

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 ☐  
Axillary ☐  
Other ☐

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 \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3862175

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3862175

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 18:37:24

Generated On: 12 Aug 2021 13:33:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	08 APR 2021
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Collection time (00:00-23:59)	13:16 (24 HR)
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Collection date and time (derived)	08 APR 2021 13:16
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US3862175

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:19:00

Generated On: 12 Aug 2021 13:33:42

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

AEID	
Adverse event	RASH [ERYTHEMATOUS AND PRURITIC] OF VACCINATED ARM
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)	13 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)	02 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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"/>

PRODUCTION RELEASE (v12.003  
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

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 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)	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

AEID

Adverse event

IPSILATERAL AXILLARY  
LYMPHADENOPATHY

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)

16 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)

25 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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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

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 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)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

AEID

Adverse event

EXACERBATION OF SEASONAL  
ALLERGIES

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)

27 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 NOV 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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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

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 type="radio"/> Not Applicable <input checked="" 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	
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)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

AEID

Adverse event

CHILBLAINS ON INDEX,  
MIDDLE AND RING FINGERS OF  
RIGHT HAND

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)

10 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 MAR 2021

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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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 18:37:19

Generated On: 12 Aug 2021 13:33:42

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:32:34

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication MULITVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR GENERAL HEALTH

Dose per administration 1

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:37:20

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Name of Medication LO LOESTRIN

Prophylaxis Yes ☐  
No ☒

Indication ENDOMETRIOSIS

Dose per administration 1

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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 2011	
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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 7.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication CLARITIN

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	1 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication CHILBAINS ON INDEX, MIDDLE,  
RING FINGERS OF RIGHT HAND

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication CLOBETASOL 0.05%

Prophylaxis Yes ☐  
No ☒

Indication CHILBAINS ON INDEX, MIDDLE,  
RING FINGERS OF RIGHT HAND

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
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"/>

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication CHILBAINS ON INDEX, MIDDLE,  
RING FINGERS OF RIGHT HAND

Dose per administration 15

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication CHILBAINS ON INDEX, MIDDLE,  
RING FINGERS OF RIGHT HAND

Dose per administration 10

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication CHILBAINS ON INDEX, MIDDLE,  
RING FINGERS OF RIGHT HAND

Dose per administration 5

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 18:37:20

Generated On: 12 Aug 2021 13:33:42

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862175

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3862175

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 02 Apr 2021 14:32:34

Generated On: 12 Aug 2021 13:33:42

Date of dosing discontinuation (dd MMM yyyy) 11 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 #1 AND #2

US3862175

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:33:42

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

US3862175 (Prod: Baylor College of Medicine)

**US3862175**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:33:42**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
	(b) (4)	
User entered 'US3862175'	RWS_ENDPOINT	11 Sep 2020 19:09:26
	ENDPOINT (b) (4)	
	(b) (4)	

US3862175

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	11 Sep 2020 20:09:01
	(b) (4)	

US3862175

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 19:09:27

US3862175

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Clinic (Clinic)'	Chanei Henry (b) (4)	11 Sep 2020 20:09:01
	(b) (4)	

**US3862175**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'SCRN'	System	11 Sep 2020 20:09:01

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered (b) (6) 1968'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 19:09:28

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '51'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	



**US3862175**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:42**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'YEARS'	System	11 Sep 2020 20:07:26

**US3862175**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:42**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '51'	System	11 Sep 2020 20:07:41

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Female (F)'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'I'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	



US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:07:26

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:42

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:07:26
	(b) (4)	

US3862175

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '11 Sep 2020'	Chanei Henry (b) (4)	11 Sep 2020 20:07:41
	(b) (4)	

**US3862175**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'Sep 2020'	System	11 Sep 2020 20:07:41

**US3862175**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '2020'	System	11 Sep 2020 20:07:41



US3862175

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Amendment 3 (3)'	Chanei Henry (b) (4)	11 Sep 2020 20:07:41
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	11 Sep 2020 20:07:41
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:07:41
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:07:41

US3862175

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	11 Sep 2020 20:07:41
	(b) (4)	

US3862175

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 19:09:27

US3862175

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:42

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '1'	System	11 Sep 2020 20:07:47

US3862175

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	11 Sep 2020 20:07:47
	(b) (4)	



US3862175

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:33:42

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:17:56

US3862175

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:19:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:19:56
Data point term sent to Coder	System	14 Sep 2020 22:19:03
User entered 'endometriosis'	Trent Davis (b) (4)	14 Sep 2020 22:18:16

US3862175

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'un UNK 2008'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:18:16

US3862175

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:18:16

US3862175

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:18:16

US3862175

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:18:16
	(b) (4)	

US3862175

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:18:16
	(b) (4)	

**US3862175**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'Jan 2008'	System	14 Sep 2020 22:18:16



**US3862175**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '2008'	System	14 Sep 2020 22:18:16

**US3862175**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	14 Sep 2020 22:18:16

**US3862175**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	14 Sep 2020 22:18:16

US3862175

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:19:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:19:56
Data point term sent to Coder	System	14 Sep 2020 22:19:04
User entered 'Acid Reflux'	Trent Davis (b) (4)	14 Sep 2020 22:18:33

US3862175

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'un UNK 2019'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:18:33

US3862175

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:18:33

US3862175

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:18:33

US3862175

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:18:33
	(b) (4)	



US3862175

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:18:33

**US3862175**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'Jan 2019'	System	14 Sep 2020 22:18:33

**US3862175**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '2019'	System	14 Sep 2020 22:18:33

**US3862175**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	14 Sep 2020 22:18:33

**US3862175**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	14 Sep 2020 22:18:33

US3862175

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:21:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:21:01
Data point term sent to Coder	System	14 Sep 2020 22:20:07
User entered 'cervical radiculopathy'	Trent Davis (b) (4)	14 Sep 2020 22:19:21
	(b) (4)	

US3862175

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'un Apr 2020'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:19:21

US3862175

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:19:21



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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:19:21

US3862175

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:19:21

US3862175

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:19:21

**US3862175**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'Apr 2020'	System	14 Sep 2020 22:19:21

**US3862175**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '2020'	System	14 Sep 2020 22:19:21

**US3862175**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	14 Sep 2020 22:19:21

**US3862175**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	14 Sep 2020 22:19:21

US3862175

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:20:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 22:20:30
Data point term sent to Coder	System	26 Oct 2020 22:19:20
User entered 'seasonal allergies'	Carrie Kibler (b) (4)	26 Oct 2020 22:18:24



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Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'un UNK 2015'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:18:24

US3862175

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:18:24

US3862175

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:18:24

US3862175

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:42

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:18:24

US3862175

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:42

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:18:24

**US3862175**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'Jan 2015'	System	26 Oct 2020 22:18:24

**US3862175**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '2015'	System	26 Oct 2020 22:18:24

**US3862175**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	26 Oct 2020 22:18:24



**US3862175**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	26 Oct 2020 22:18:24

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '11 Sep 2020'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '13:43'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

**US3862175**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '11 Sep 2020 13:43'	System	11 Sep 2020 20:10:11

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '161.0' cm	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:10:11
DataPoint set to visible.	(b) (4) System	11 Sep 2020 20:07:47

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '108.5' lb	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:10:11
DataPoint set to visible.	(b) (4) System	11 Sep 2020 20:07:47

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '19.02634'	System	11 Sep 2020 20:10:11
DataPoint set to visible.	System	11 Sep 2020 20:07:47



**US3862175**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'kg/m2'	System	11 Sep 2020 20:10:11
DataPoint set to visible.	System	11 Sep 2020 20:07:47

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '97.8' F	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'Oral (Oral)'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '72'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

**US3862175**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'bpm'	System	11 Sep 2020 20:10:11

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '16'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'breaths/min'	System	11 Sep 2020 20:10:11



US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '113'	Chanei Henry (b) (4)	11 Sep 2020 20:10:11
	(b) (4)	

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mmHg'	System	11 Sep 2020 20:10:11

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '69'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:10:11

US3862175

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mmHg'	System	11 Sep 2020 20:10:11

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01

US3862175

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	11 Sep 2020 20:10:28
	(b) (4)	

**US3862175**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:33:42**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '11 Sep 2020'	Chanei Henry (b) (4)	11 Sep 2020 20:10:28
	(b) (4)	



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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '11 Sep 2020'	Chanei Henry (b) (4)	11 Sep 2020 20:11:03
	(b) (4)	

US3862175

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03

US3862175

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03

US3862175

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:33:42

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:03



US3862175

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	11 Sep 2020 20:11:22
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '11 Sep 2020'	Chanei Henry (b) (4)	11 Sep 2020 20:11:22
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Urine (URINE)'	Chanei Henry (b) (4)	11 Sep 2020 20:11:22
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Chanei Henry (b) (4)	11 Sep 2020 20:11:22
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:58:00
Signature has been broken.	(b) (4)	
	Sandra Francisco (b) (4)	05 Mar 2021 18:37:11
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Francisco (b) (4)	05 Mar 2021 18:37:11
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	11 Sep 2020 20:11:22
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:22

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:11:22

**US3862175**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	11 Sep 2020 20:11:22



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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Research Lab Personnel'	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

**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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'I'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '0'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:13:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	11 Sep 2020 20:13:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:06:38

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:06:38
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Clinic (Clinic)'	(b) (4) Chanei Henry (b) (4)	11 Sep 2020 20:06:38
	(b) (4)	



**US3862175**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'VISIT1'	System	11 Sep 2020 20:06:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 20:09:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '113466'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 20:09:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '>=18 and <65 years and not at risk (1)'	(b) (4)	11 Sep 2020 20:09:23
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

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)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:41

US3862175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

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)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'No (N)'	Trent Davis (b) (4)	14 Sep 2020 22:17:41

US3862175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:41

US3862175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:41



US3862175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:17:41

US3862175

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:42

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	22 Sep 2020 19:09:24
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:15:00
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:14:58

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:18:59
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:37:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:37:45
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:35:18
User entered '161.0' cm	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:37:45
User entered '108.5' lb	Shetel Anassi (b) (4)	14 Sep 2020 22:23:32
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4)	22 Oct 2020 15:18:59
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:37:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:37:45
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:35:18
User entered '161.0' cm	Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:37:45
User entered '108.5' lb	Shetel Anassi (b) (4)	14 Sep 2020 22:23:32
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '13:43'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '11 Sep 2020 13:43'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '97.8' F	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '072'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'bpm'	System	14 Sep 2020 22:23:32



US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '016'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'breaths/min'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '113'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '069'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:58:49
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:18:59
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:37:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:37:45
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:35:18
User entered '161.0' cm	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:37:45
User entered '108.5' lb	Shetel Anassi (b) (4)	14 Sep 2020 22:23:32
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '15:57'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '11 Sep 2020 15:57'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '97.9' F	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:32



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '061'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'bpm'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '016'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'breaths/min'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '131'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '081'	(b) (4) Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:23:32

US3862175

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	14 Sep 2020 22:23:32



US3862175

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:29:12

US3862175

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:29:12

US3862175

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User closed query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark response for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 10:41:23
Query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark response for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you. ' answered with 'Deleted ' (Site from DM).	Chanei Henry (b) (4)	05 Oct 2020 16:57:42
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	05 Oct 2020 16:57:30
User opened query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark response for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:39:22
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	11 Sep 2020 20:30:45

US3862175

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty; reason for change Per Query Resolution	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 16:57:30
User entered '11 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:30:45
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Chanei Henry (b) (4)	05 Oct 2020 16:57:30
	(b) (4)	
User entered 'Urine (URINE)'	Sandra Francisco (b) (4)	11 Sep 2020 20:30:45
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty; reason for change Per Query Resolution	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 16:57:30
User entered 'Negative (NEGATIVE)'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:30:45
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Chanei Henry (b) (4)	05 Oct 2020 16:57:30
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	11 Sep 2020 20:30:45
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Chanei Henry (b) (4)	05 Oct 2020 16:57:30
	(b) (4)	
User entered '11 Sep 2020'	Sandra Francisco (b) (4)	11 Sep 2020 20:30:45
	(b) (4)	



US3862175

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty; reason for change Per Query Resolution	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 16:57:30
User entered '14:59'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:30:45
	(b) (4)	

**US3862175**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	05 Oct 2020 16:57:30
User entered '11 Sep 2020 14:59'	System	11 Sep 2020 20:30:45

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

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 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '15:25'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:09



US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '11 Sep 2020 15:25'	System	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'ONCE'	System	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 20:31:09

US3862175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:34

US3862175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:34

US3862175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '14:37'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:34

US3862175

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '11 Sep 2020 14:37'	System	11 Sep 2020 20:31:34



US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:33:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '11 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:49

US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sandra Francisco (b) (4)	11 Sep 2020 20:31:49

US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:49

US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '14:15'	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:49

**US3862175**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '11 Sep 2020 14:15'	System	11 Sep 2020 20:31:49

US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sandra Francisco (b) (4)	11 Sep 2020 20:31:49

US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 20:31:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 20:31:55
User entered 'No (N)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	11 Sep 2020 20:31:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 20:31:49
User entered empty.	System	11 Sep 2020 20:31:49
	Sandra Francisco (b) (4)	11 Sep 2020 20:31:49
	(b) (4)	

US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Sandra Francisco (b) (4)	11 Sep 2020 20:31:49



US3862175

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	11 Sep 2020 20:31:49

US3862175

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	14 Sep 2020 22:23:37

US3862175

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '1'	System	14 Sep 2020 22:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:49:39', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3c4264fa-7b22-4c6d-9f57-6c46eda50f0b' User entered 'Yes (Y)'	System	11 Sep 2020 20:50:06
	System	11 Sep 2020 20:50:06

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:49:47', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3c4264fa-7b22-4c6d-9f57-6c46eda50f0b' User entered '97.9'	System	11 Sep 2020 20:50:06
	System	11 Sep 2020 20:50:06

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:49:52', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3c4264fa-7b22-4c6d-9f57-6c46eda50f0b' User entered 'No (N)'	System	11 Sep 2020 20:50:06
	System	11 Sep 2020 20:50:06

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:04', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3c4264fa-7b22-4c6d-9f57-6c46eda50f0b' User entered '11 Sep 2020 15:50'	System	11 Sep 2020 20:50:06
	System	11 Sep 2020 20:50:06



US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 15:45'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 18:15'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:35', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '85c866ab-bdb9-4df9-8f1a-295c5de95e39' User entered 'Yes (Y)'	System	12 Sep 2020 01:52:50
	System	12 Sep 2020 01:52:50

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:41', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '85c866ab-bdb9-4df9-8f1a-295c5de95e39' User entered '98.1'	System	12 Sep 2020 01:52:50
	System	12 Sep 2020 01:52:50

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:44', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '85c866ab-bdb9-4df9-8f1a-295c5de95e39' User entered 'No (N)'	System	12 Sep 2020 01:52:50
	System	12 Sep 2020 01:52:50

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:49', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '85c866ab-bdb9-4df9-8f1a-295c5de95e39' User entered '11 Sep 2020 20:52'	System	12 Sep 2020 01:52:50
	System	12 Sep 2020 01:52:50

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 19:10'	System	11 Sep 2020 20:31:09



US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 2'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:44', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1c78f876-9c1b-4d76-a16a-4e63117f1559' User entered 'Yes (Y)'	System	12 Sep 2020 19:32:34
	System	12 Sep 2020 19:32:34

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:32:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1c78f876-9c1b-4d76-a16a-4e63117f1559' User entered '97.8'	System	12 Sep 2020 19:32:34
	System	12 Sep 2020 19:32:34

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:32:26', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1c78f876-9c1b-4d76-a16a-4e63117f1559'	System	12 Sep 2020 19:32:34
User entered 'No (N)'	System	12 Sep 2020 19:32:34

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:32:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1c78f876-9c1b-4d76-a16a-4e63117f1559' User entered '12 Sep 2020 14:32'	System	12 Sep 2020 19:32:34
	System	12 Sep 2020 19:32:34

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:31:09



US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 3'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:02', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '8d9e1f81-8107-4855-b707-b08b78062b8b' User entered 'Yes (Y)'	System	13 Sep 2020 18:58:19
	System	13 Sep 2020 18:58:19

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:11', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '8d9e1f81-8107-4855-b707-b08b78062b8b' User entered '98.0'	System	13 Sep 2020 18:58:19
	System	13 Sep 2020 18:58:19

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:13', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '8d9e1f81-8107-4855-b707-b08b78062b8b' User entered 'No (N)'	System	13 Sep 2020 18:58:19
	System	13 Sep 2020 18:58:19

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:16', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '8d9e1f81-8107-4855-b707-b08b78062b8b' User entered '13 Sep 2020 13:58'	System	13 Sep 2020 18:58:19
	System	13 Sep 2020 18:58:19

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 4'	System	11 Sep 2020 20:31:09



US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:04:33', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c2f121dc-4b4b-46d4-b204-84a17a5215c3' User entered 'Yes (Y)'	System	15 Sep 2020 01:04:54
	System	15 Sep 2020 01:04:54

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:04:46', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c2f121dc-4b4b-46d4-b204-84a17a5215c3' User entered '97.9'	System	15 Sep 2020 01:04:54
	System	15 Sep 2020 01:04:54

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:04:49', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c2f121dc-4b4b-46d4-b204-84a17a5215c3'	System	15 Sep 2020 01:04:54
User entered 'No (N)'	System	15 Sep 2020 01:04:54

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:04:52', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c2f121dc-4b4b-46d4-b204-84a17a5215c3' User entered '14 Sep 2020 20:04'	System	15 Sep 2020 01:04:54
	System	15 Sep 2020 01:04:54

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 5'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:22:25', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '89ba41f1-8adf-4672-b956-cbb3064f9a21' User entered 'Yes (Y)'	System	16 Sep 2020 03:22:45
	System	16 Sep 2020 03:22:45



US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:22:32', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '89ba41f1-8adf-4672-b956-cbb3064f9a21' User entered '97.8'	System	16 Sep 2020 03:22:45
	System	16 Sep 2020 03:22:45

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:22:37', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '89ba41f1-8adf-4672-b956-cbb3064f9a21' User entered 'No (N)'	System	16 Sep 2020 03:22:45
	System	16 Sep 2020 03:22:45

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:22:40', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '89ba41f1-8adf-4672-b956-cbb3064f9a21' User entered '15 Sep 2020 22:22'	System	16 Sep 2020 03:22:45
	System	16 Sep 2020 03:22:45

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 6'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:24', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6e5a2cfc-9433-48d6-b94f-961580ba71f2' User entered 'Yes (Y)'	System	16 Sep 2020 23:44:41
	System	16 Sep 2020 23:44:41

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:31', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6e5a2cfc-9433-48d6-b94f-961580ba71f2' User entered '98.0'	System	16 Sep 2020 23:44:41
	System	16 Sep 2020 23:44:41



US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:34', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6e5a2cfc-9433-48d6-b94f-961580ba71f2'	System	16 Sep 2020 23:44:41
User entered 'No (N)'	System	16 Sep 2020 23:44:41

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:37', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6e5a2cfc-9433-48d6-b94f-961580ba71f2'	System	16 Sep 2020 23:44:41
User entered '16 Sep 2020 18:44'	System	16 Sep 2020 23:44:41

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 7'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:38', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '167be4bc-d998-4033-82cf-71358aa8439a' User entered 'Yes (Y)'	System	18 Sep 2020 02:30:53
	System	18 Sep 2020 02:30:53

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:43', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '167be4bc-d998-4033-82cf-71358aa8439a' User entered '98.0'	System	18 Sep 2020 02:30:53
	System	18 Sep 2020 02:30:53

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:46', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '167be4bc-d998-4033-82cf-71358aa8439a' User entered 'No (N)'	System	18 Sep 2020 02:30:53
	System	18 Sep 2020 02:30:53



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:49', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '167be4bc-d998-4033-82cf-71358aa8439a' User entered '17 Sep 2020 21:30'	System	18 Sep 2020 02:30:53
	System	18 Sep 2020 02:30:53

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:34', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '55b00eae-93e2-462d-a3e9-f70bcd6ff381'	System	11 Sep 2020 20:50:50
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 20:50:50

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:38', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '55b00eae-93e2-462d-a3e9-f70bcd6ff381' User entered 'No (N)'	System	11 Sep 2020 20:50:50
	System	11 Sep 2020 20:50:50

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:41', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '55b00eae-93e2-462d-a3e9-f70bcd6ff381' User entered 'No (N)'	System	11 Sep 2020 20:50:50
	System	11 Sep 2020 20:50:50

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:44', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '55b00eae-93e2-462d-a3e9-f70bcd6ff381' User entered 'None (1)'	System	11 Sep 2020 20:50:50
	System	11 Sep 2020 20:50:50



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:48', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '55b00eae-93e2-462d-a3e9-f70bcd6ff381' User entered '11 Sep 2020 15:50'	System	11 Sep 2020 20:50:50
	System	11 Sep 2020 20:50:50

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 15:45'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 18:15'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:53', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c512f49e-97c8-4f43-954e-8bb0b3d489f8'	System	12 Sep 2020 01:53:07
User entered 'None (1)'	System	12 Sep 2020 01:53:07

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:56', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c512f49e-97c8-4f43-954e-8bb0b3d489f8' User entered 'No (N)'	System	12 Sep 2020 01:53:07
	System	12 Sep 2020 01:53:07

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:52:59', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c512f49e-97c8-4f43-954e-8bb0b3d489f8' User entered 'No (N)'	System	12 Sep 2020 01:53:07
	System	12 Sep 2020 01:53:07

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:03', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c512f49e-97c8-4f43-954e-8bb0b3d489f8'	System	12 Sep 2020 01:53:07
User entered 'None (1)'	System	12 Sep 2020 01:53:07



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:05', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c512f49e-97c8-4f43-954e-8bb0b3d489f8' User entered '11 Sep 2020 20:53'	System	12 Sep 2020 01:53:07
	System	12 Sep 2020 01:53:07

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 19:10'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 2'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:30:52', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0a9161e5-34d0-440b-bf13-61b5b77515de' User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 19:31:08
	System	12 Sep 2020 19:31:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:30:55', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0a9161e5-34d0-440b-bf13-61b5b77515de' User entered 'No (N)'	System	12 Sep 2020 19:31:08
	System	12 Sep 2020 19:31:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:30:59', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0a9161e5-34d0-440b-bf13-61b5b77515de' User entered 'No (N)'	System	12 Sep 2020 19:31:08
	System	12 Sep 2020 19:31:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:03', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0a9161e5-34d0-440b-bf13-61b5b77515de' User entered 'None (1)'	System	12 Sep 2020 19:31:08
	System	12 Sep 2020 19:31:08



US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:06', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0a9161e5-34d0-440b-bf13-61b5b77515de' User entered '12 Sep 2020 14:31'	System	12 Sep 2020 19:31:08
	System	12 Sep 2020 19:31:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 3'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96d00520-ac53-4caf-95c8-26d2236220b7'	System	13 Sep 2020 18:58:47
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 18:58:47

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:31', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96d00520-ac53-4caf-95c8-26d2236220b7' User entered 'No (N)'	System	13 Sep 2020 18:58:47
	System	13 Sep 2020 18:58:47

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:33', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96d00520-ac53-4caf-95c8-26d2236220b7' User entered 'No (N)'	System	13 Sep 2020 18:58:47
	System	13 Sep 2020 18:58:47

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:35', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96d00520-ac53-4caf-95c8-26d2236220b7' User entered 'None (1)'	System	13 Sep 2020 18:58:47
	System	13 Sep 2020 18:58:47



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:37', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96d00520-ac53-4caf-95c8-26d2236220b7' User entered '13 Sep 2020 13:58'	System	13 Sep 2020 18:58:47
	System	13 Sep 2020 18:58:47

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 4'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:05:23', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96b293ef-f218-4f50-8572-d0160573fb3b' User entered 'None (1)'	System	15 Sep 2020 01:06:51
	System	15 Sep 2020 01:06:51

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:05:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96b293ef-f218-4f50-8572-d0160573fb3b' User entered 'Yes (Y)'	System	15 Sep 2020 01:06:51
	System	15 Sep 2020 01:06:51

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:08', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96b293ef-f218-4f50-8572-d0160573fb3b' User entered '5'	System	15 Sep 2020 01:06:51
	System	15 Sep 2020 01:06:51

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:30', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96b293ef-f218-4f50-8572-d0160573fb3b' User entered 'No (N)'	System	15 Sep 2020 01:06:51
	System	15 Sep 2020 01:06:51



US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:34', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96b293ef-f218-4f50-8572-d0160573fb3b' User entered 'None (1)'	System	15 Sep 2020 01:06:51
	System	15 Sep 2020 01:06:51

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:48', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '96b293ef-f218-4f50-8572-d0160573fb3b' User entered '14 Sep 2020 20:06'	System	15 Sep 2020 01:06:51
	System	15 Sep 2020 01:06:51

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 5'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:22:46', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c24bf4af-0659-49dd-b569-52fe05e3a1f4' User entered 'None (1)'	System	16 Sep 2020 03:23:15
	System	16 Sep 2020 03:23:15

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c24bf4af-0659-49dd-b569-52fe05e3a1f4' User entered 'No (N)'	System	16 Sep 2020 03:23:15
	System	16 Sep 2020 03:23:15

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:03', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c24bf4af-0659-49dd-b569-52fe05e3a1f4' User entered 'No (N)'	System	16 Sep 2020 03:23:15
	System	16 Sep 2020 03:23:15



US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:07', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c24bf4af-0659-49dd-b569-52fe05e3a1f4' User entered 'None (1)'	System	16 Sep 2020 03:23:15
	System	16 Sep 2020 03:23:15

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:13', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c24bf4af-0659-49dd-b569-52fe05e3a1f4' User entered '15 Sep 2020 22:23'	System	16 Sep 2020 03:23:15
	System	16 Sep 2020 03:23:15

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 6'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:43', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '012f0ba6-c206-4a6b-926f-95a8db1790e6'	System	16 Sep 2020 23:45:08
User entered 'None (1)'	System	16 Sep 2020 23:45:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:46', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '012f0ba6-c206-4a6b-926f-95a8db1790e6' User entered 'No (N)'	System	16 Sep 2020 23:45:08
	System	16 Sep 2020 23:45:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:44:51', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '012f0ba6-c206-4a6b-926f-95a8db1790e6' User entered 'No (N)'	System	16 Sep 2020 23:45:08
	System	16 Sep 2020 23:45:08



US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '012f0ba6-c206-4a6b-926f-95a8db1790e6'	System	16 Sep 2020 23:45:08
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 23:45:08

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:07', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '012f0ba6-c206-4a6b-926f-95a8db1790e6' User entered '16 Sep 2020 18:45'	System	16 Sep 2020 23:45:08
	System	16 Sep 2020 23:45:08

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 7'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:53', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '06f71650-cddd-42c3-8943-53c564909bed' User entered 'None (1)'	System	18 Sep 2020 02:31:20
	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:56', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '06f71650-cddd-42c3-8943-53c564909bed' User entered 'No (N)'	System	18 Sep 2020 02:31:20
	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:30:59', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '06f71650-cddd-42c3-8943-53c564909bed' User entered 'No (N)'	System	18 Sep 2020 02:31:20
	System	18 Sep 2020 02:31:20



US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:05', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '06f71650-cddd-42c3-8943-53c564909bed' User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 02:31:20
	System	18 Sep 2020 02:31:20

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:16', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '06f71650-cddd-42c3-8943-53c564909bed' User entered '17 Sep 2020 21:31'	System	18 Sep 2020 02:31:20
	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:53', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'None (0)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:55', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'None (0)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:57', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'None (0)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:50:59', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'None (0)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:33:42**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:51:01', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'None (0)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:33:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:51:03', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'None (0)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:51:06', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered 'No (N)'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T15:51:10', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'bc918f59-9a43-42b4-b52c-957d98224e0a' User entered '11 Sep 2020 15:51'	System	11 Sep 2020 20:51:13
	System	11 Sep 2020 20:51:13

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 15:45'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 18:15'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:31:09



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:09', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'None (0)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:11', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'None (0)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:13', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'None (0)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:15', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'None (0)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:17', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'None (0)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:19', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'None (0)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:23', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered 'No (N)'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-11T20:53:25', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '48dabc0f-461a-42e3-a486-bf78996f77be' User entered '11 Sep 2020 20:53'	System	12 Sep 2020 01:53:28
	System	12 Sep 2020 01:53:28



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '11 Sep 2020 19:10'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 2'	System	11 Sep 2020 20:31:09

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:33:42**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:17', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65'	System	12 Sep 2020 19:31:39
User entered 'No interference with activity (1)'	System	12 Sep 2020 19:31:39

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:33:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:20', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered 'None (0)'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:25', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered 'None (0)'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered 'None (0)'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:30', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered 'None (0)'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:33:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:33', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered 'None (0)'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:35', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered 'No (N)'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-12T14:31:37', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'daeb65c0-d4d5-404b-bb2f-223d546e0c65' User entered '12 Sep 2020 14:31'	System	12 Sep 2020 19:31:39
	System	12 Sep 2020 19:31:39

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 3'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:41', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'None (0)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:43', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'None (0)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:47', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'None (0)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:49', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'None (0)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:51', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'None (0)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:58:57', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'None (0)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:59:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered 'No (N)'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-13T13:59:03', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1f2f36bd-aa9f-4491-85b3-cc781fcb1193' User entered '13 Sep 2020 13:59'	System	13 Sep 2020 18:59:52
	System	13 Sep 2020 18:59:52

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:31:09



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 4'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:52', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'None (0)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:54', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'None (0)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:06:57', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'None (0)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:07:09', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'No interference with activity (1)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:07:12', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'None (0)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:07:14', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'None (0)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:07:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered 'No (N)'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-14T20:07:45', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'e18adb00-2378-49a3-a717-baae06d65bba' User entered '14 Sep 2020 20:07'	System	15 Sep 2020 01:07:48
	System	15 Sep 2020 01:07:48

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 5'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:20', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'None (0)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'None (0)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:24', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'None (0)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:27', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'None (0)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:29', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'None (0)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:31', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'None (0)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:33', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered 'No (N)'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-15T22:23:36', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '0272c5fc-15a6-4cc7-a127-2f232ca070cc' User entered '15 Sep 2020 22:23'	System	16 Sep 2020 03:23:37
	System	16 Sep 2020 03:23:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 6'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:10', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'None (0)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:12', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'None (0)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:14', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'None (0)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:16', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'None (0)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:19', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'None (0)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:20', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'None (0)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered 'No (N)'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-16T18:45:35', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '5b551368-705c-4725-a979-975deb7aa944' User entered '16 Sep 2020 18:45'	System	16 Sep 2020 23:45:37
	System	16 Sep 2020 23:45:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:31:09



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 7'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:20', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'None (0)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:21', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'None (0)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:24', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'None (0)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:25', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'None (0)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:27', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'None (0)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:30', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'None (0)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37



US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:32', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered 'No (N)'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-17T21:31:35', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '1eddf5d6-22cc-4bcd-a446-2ac4569c9046' User entered '17 Sep 2020 21:31'	System	18 Sep 2020 02:31:37
	System	18 Sep 2020 02:31:37

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:31:09

US3862175

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	18 Sep 2020 02:31:20
User entered 'Day 9'	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-19T12:08:50', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c38efe9e-8b56-4072-9bea-8c659d7adfd3'	System	19 Sep 2020 17:08:58
User entered 'No (N)'	System	19 Sep 2020 17:08:58

US3862175

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:33:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-19T12:08:55', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c38efe9e-8b56-4072-9bea-8c659d7adfd3' User entered '19 Sep 2020 12:08'	System	19 Sep 2020 17:08:58
	System	19 Sep 2020 17:08:58

US3862175

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 02:31:20



US3862175

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	16 Sep 2020 23:45:08
User entered 'Day 8'	System	16 Sep 2020 23:45:08

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-18T17:50:23', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '62114638-78c1-42e8-a8ec-3803f74fd31d'	System	18 Sep 2020 22:50:36
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 22:50:36

**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(8)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-18T17:50:32', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '62114638-78c1-42e8-a8ec-3803f74fd31d' User entered '18 Sep 2020 17:50'	System	18 Sep 2020 22:50:36
	System	18 Sep 2020 22:50:36

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 23:45:08

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(8)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 23:45:08

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 12 Aug 2021 13:33:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	18 Sep 2020 02:31:20
User entered 'Day 9'	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 12 Aug 2021 13:33:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-19T12:09:18', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '57bdd4d5-1c92-4d2f-8de2-d4a57f23b7ac' User entered 'None (1)'	System	19 Sep 2020 17:09:50
	System	19 Sep 2020 17:09:50



**US3862175**

**Folder: Diary Dose 1 (1)**

**Form: Underarm Gland\_Day(9)**

**Generated On: 12 Aug 2021 13:33:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-09-19T12:09:21', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '57bdd4d5-1c92-4d2f-8de2-d4a57f23b7ac' User entered '19 Sep 2020 12:09'	System	19 Sep 2020 17:09:50
	System	19 Sep 2020 17:09:50

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 12 Aug 2021 13:33:42

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 02:31:20

US3862175

Folder: Diary Dose 1 (1)

Form: Underarm Gland\_Day(9)

Generated On: 12 Aug 2021 13:33:42

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 02:31:20

US3862175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 22:39:23

US3862175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '18 Sep 2020'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 22:39:23
	(b) (4)	

US3862175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 22:39:23

US3862175

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 22:39:23
	(b) (4)	

US3862175

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	18 Sep 2020 22:39:34



US3862175

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	18 Sep 2020 22:39:34

**US3862175**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	25 Sep 2020 22:56:12

US3862175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '25 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 22:56:12

US3862175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 22:56:12

US3862175

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 22:56:12

US3862175

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	05 Oct 2020 17:05:49
	(b) (4)	

**US3862175**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	05 Oct 2020 17:05:49

US3862175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 17:06:19



US3862175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '02 Oct 2020'	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 17:06:19
	(b) (4)	

US3862175

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 17:06:19

**US3862175**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 17:06:19
	(b) (4)	

US3862175

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	05 Oct 2020 17:06:24

**US3862175**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	05 Oct 2020 17:06:24

US3862175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:56:57

US3862175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '9 Oct 2020'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:56:57
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Clinic (Clinic)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:56:57
	(b) (4)	



**US3862175**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'VISIT2'	System	09 Oct 2020 18:56:57

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Pre-Dose (PREDOSE)'	Chaneí Henry (b) (4) (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '9 Oct 2020'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '13:05'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '9 Oct 2020 13:05'	System	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered '97.4' F	Chanei Henry (b) (4)	09 Oct 2020 18:58:12
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Other (Other)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Temporal'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '69'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'bpm'	System	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '12'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'breaths/min'	System	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '121'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '85'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:12



US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	09 Oct 2020 18:58:12

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Post-Dose (POSTDOSE)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	09 Oct 2020 18:58:20
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20



US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

**US3862175**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:58:20



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:58:20

US3862175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	09 Oct 2020 18:58:32
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
Signature has been broken.	(b) (4)	05 Mar 2021 18:36:39
	Sandra Francisco (b) (4)	05 Mar 2021 18:36:39
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	05 Mar 2021 18:36:39
User signature succeeded.	Sandra Francisco (b) (4)	05 Mar 2021 18:36:39
	(b) (4)	13 Feb 2021 00:58:49
User entered '9 Oct 2020'	Hana El Sahly (b) (4)	09 Oct 2020 18:58:32
	(b) (4)	
	Chanei Henry (b) (4)	
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:31

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '9 Oct 2020'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:31
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'Urine (URINE)'	Chanei Henry (b) (4)	09 Oct 2020 18:59:31
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Negative (NEGATIVE)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:31

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	09 Oct 2020 18:59:31
	(b) (4)	



US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:31

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:31

US3862175

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:59:31

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	09 Oct 2020 18:59:45
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Chanei Henry (b) (4)	09 Oct 2020 18:59:45
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

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 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:45
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:59:45

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:45



US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:45

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:59:45

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 18:59:45

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:59:45

US3862175

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 18:59:45

US3862175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:03

US3862175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '9 Oct 2020'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:03
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '13:53'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:03



US3862175

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '9 Oct 2020 13:53'	System	09 Oct 2020 19:00:03

US3862175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:33:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '9 Oct 2020'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:38

**US3862175**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:00:38

US3862175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	09 Oct 2020 19:00:38
	(b) (4)	

US3862175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:38

**US3862175**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered empty.	System	09 Oct 2020 19:00:38

US3862175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:00:38

US3862175

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:38



**US3862175**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '13:47'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:38

**US3862175**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '9 Oct 2020 13:47'	System	09 Oct 2020 19:00:38

US3862175

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Oct 2020 19:00:43

US3862175

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	09 Oct 2020 19:00:43

**US3862175**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Oct 2020 19:59:22

US3862175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered '19 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Oct 2020 19:59:22

US3862175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Oct 2020 19:59:22

US3862175

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4)	20 Oct 2020 19:59:35
Please review and reconcile.' (Site from System).		
User entered 'WOULD NOT RESPOND TO PHONE CALLS' reason for change: Data Entry Error	Carrie Kibler (b) (4)	20 Oct 2020 19:59:35
	(b) (4)	
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	20 Oct 2020 19:59:22
Please review and reconcile.' (Site from System).		
User entered empty.	Carrie Kibler (b) (4)	20 Oct 2020 19:59:22
	(b) (4)	



US3862175

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	20 Oct 2020 19:59:41

**US3862175**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	20 Oct 2020 19:59:41

**US3862175**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:15:10

US3862175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '26 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:15:10

US3862175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:15:10

US3862175

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:15:10

US3862175

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:15:20

US3862175

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	26 Oct 2020 22:15:20



**US3862175**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	30 Oct 2020 17:17:24

US3862175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered '30 Oct 2020'	(b) (4) Chanei Henry (b) (4)	30 Oct 2020 17:17:24
	(b) (4)	

US3862175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	30 Oct 2020 17:17:24

US3862175

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	30 Oct 2020 17:17:24
	(b) (4)	

US3862175

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	30 Oct 2020 17:17:29

**US3862175**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	30 Oct 2020 17:17:29

US3862175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:07:51

US3862175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:07:51



US3862175

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:07:51

**US3862175**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'VISIT3'	System	06 Nov 2020 20:07:51

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '13:08'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

**US3862175**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '6 Nov 2020 13:08'	System	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '97.3' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05



US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '69'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

**US3862175**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'bpm'	System	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '12'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'breaths/min'	System	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '112'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '79'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:05



**US3862175**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'mmHg'	System	06 Nov 2020 20:10:05

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39

US3862175

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39

US3862175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:08:08

US3862175

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:08:08

US3862175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:09:07

US3862175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '6 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:09:07

US3862175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered '13:35'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:09:07



US3862175

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered '6 Nov 2020 13:35'	System	06 Nov 2020 20:09:07

US3862175

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:58:49
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:07:58

**US3862175**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	06 Nov 2020 20:07:58

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 64'	System	11 Sep 2020 20:31:09

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-13T10:19:10', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '541fb989-1f95-46b9-874e-1aa579a1a438' User entered 'No (N)'	System	13 Nov 2020 16:19:25
	System	13 Nov 2020 16:19:25

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-13T10:19:14', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '541fb989-1f95-46b9-874e-1aa579a1a438'	System	13 Nov 2020 16:19:25
User entered 'No (N)'	System	13 Nov 2020 16:19:25

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-13T10:19:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '541fb989-1f95-46b9-874e-1aa579a1a438' User entered '13 Nov 2020 10:19:22'	System	13 Nov 2020 16:19:25
	System	13 Nov 2020 16:19:25

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 20:31:09



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:54:27
Data entry locked.	System	11 Sep 2020 20:31:09
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 20:31:09

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13
Data entry locked.	System	11 Sep 2020 20:31:09
User entered 'Day 71'	System	11 Sep 2020 20:31:09

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Please 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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13



US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Please 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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13



US3862175

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:42

[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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Please 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 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13
Data entry locked.	System	11 Sep 2020 20:31:09
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 20:31:09

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:13
Data entry locked.	System	11 Sep 2020 20:31:09
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 20:31:09

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-24T13:59:14', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'd4c21c8b-43f6-4c89-86f3-ed13072a1a98' User entered 'No (N)'	System	24 Nov 2020 19:59:26
	System	24 Nov 2020 19:59:26

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-24T13:59:19', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'd4c21c8b-43f6-4c89-86f3-ed13072a1a98' User entered 'No (N)'	System	24 Nov 2020 19:59:26



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-24T13:59:23', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'd4c21c8b-43f6-4c89-86f3-ed13072a1a98' User entered '24 Nov 2020 13:59:23'	System	24 Nov 2020 19:59:26
	System	24 Nov 2020 19:59:26

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-29T13:50:32', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a790fde7-9860-4c32-9412-5eafa6748c9b' User entered 'No (N)'	System	29 Nov 2020 19:50:43

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-29T13:50:36', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a790fde7-9860-4c32-9412-5eafa6748c9b' User entered 'No (N)'	System	29 Nov 2020 19:50:43

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-11-29T13:50:40', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a790fde7-9860-4c32-9412-5eafa6748c9b' User entered '29 Nov 2020 13:50:40'	System	29 Nov 2020 19:50:43

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-08T09:54:50', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '099088b7-53d1-43ca-bb3a-c5bc19b529e4' User entered 'No (N)'	System	08 Dec 2020 15:54:59
	System	08 Dec 2020 15:54:59

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-08T09:54:54', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '099088b7-53d1-43ca-bb3a-c5bc19b529e4'	System	08 Dec 2020 15:54:59
User entered 'No (N)'	System	08 Dec 2020 15:54:59

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-08T09:54:57', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '099088b7-53d1-43ca-bb3a-c5bc19b529e4' User entered '08 Dec 2020 09:54:57'	System	08 Dec 2020 15:54:59
	System	08 Dec 2020 15:54:59

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-16T16:10:53', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '07f713e3-eeb4-4242-b91e-dbfce2ab96de'	System	16 Dec 2020 22:11:02
User entered 'No (N)'	System	16 Dec 2020 22:11:02

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-16T16:10:56', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '07f713e3-eeb4-4242-b91e-dbfce2ab96de'	System	16 Dec 2020 22:11:02
User entered 'No (N)'	System	16 Dec 2020 22:11:02

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-16T16:10:59', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '07f713e3-eeb4-4242-b91e-dbfce2ab96de' User entered '16 Dec 2020 16:10:59'	System	16 Dec 2020 22:11:02
	System	16 Dec 2020 22:11:02

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-21T09:16:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'f59d5e42-5a6e-4178-bd2a-09233850cb3c' User entered 'No (N)'	System	21 Dec 2020 15:16:37
	System	21 Dec 2020 15:16:37

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-21T09:16:25', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'f59d5e42-5a6e-4178-bd2a-09233850cb3c' User entered 'No (N)'	System	21 Dec 2020 15:16:37
	System	21 Dec 2020 15:16:37



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-21T09:16:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'f59d5e42-5a6e-4178-bd2a-09233850cb3c' User entered '21 Dec 2020 09:16:28'	System	21 Dec 2020 15:16:37
	System	21 Dec 2020 15:16:37

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-28T18:57:32', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '549d3167-9b2a-4205-887c-77f428363ccb' User entered 'No (N)'	System	29 Dec 2020 00:57:48
	System	29 Dec 2020 00:57:48

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-28T18:57:38', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '549d3167-9b2a-4205-887c-77f428363ccb' User entered 'No (N)'	System	29 Dec 2020 00:57:48

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2020-12-28T18:57:42', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '549d3167-9b2a-4205-887c-77f428363ccb' User entered '28 Dec 2020 18:57:42'	System	29 Dec 2020 00:57:48
	System	29 Dec 2020 00:57:48

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-03T21:10:11', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'ffa6fe9c-33ee-47dd-bb98-3edb24d2b898'	System	04 Jan 2021 03:10:23
User entered 'No (N)'	System	04 Jan 2021 03:10:23

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-03T21:10:18', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'ffa6fe9c-33ee-47dd-bb98-3edb24d2b898'	System	04 Jan 2021 03:10:23
User entered 'No (N)'	System	04 Jan 2021 03:10:23

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-03T21:10:22', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'ffa6fe9c-33ee-47dd-bb98-3edb24d2b898' User entered '03 Jan 2021 21:10:22'	System	04 Jan 2021 03:10:23
	System	04 Jan 2021 03:10:23

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-10T14:46:43', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c782e536-9c3c-4fed-9940-b7619fc10ac4' User entered 'No (N)'	System	10 Jan 2021 20:46:51
	System	10 Jan 2021 20:46:51

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-10T14:46:46', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c782e536-9c3c-4fed-9940-b7619fc10ac4'	System	10 Jan 2021 20:46:51
User entered 'No (N)'	System	10 Jan 2021 20:46:51

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-10T14:46:48', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c782e536-9c3c-4fed-9940-b7619fc10ac4' User entered '10 Jan 2021 14:46:48'	System	10 Jan 2021 20:46:51
	System	10 Jan 2021 20:46:51

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-20T18:37:23', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '84b6a94f-6df7-4e9b-a591-d334d163858e' User entered 'No (N)'	System	21 Jan 2021 00:37:36
	System	21 Jan 2021 00:37:36

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-20T18:37:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '84b6a94f-6df7-4e9b-a591-d334d163858e' User entered 'No (N)'	System	21 Jan 2021 00:37:36
	System	21 Jan 2021 00:37:36



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-20T18:37:32', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '84b6a94f-6df7-4e9b-a591-d334d163858e' User entered '20 Jan 2021 18:37:32'	System	21 Jan 2021 00:37:36
	System	21 Jan 2021 00:37:36

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-25T18:59:45', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3b02b53c-eea9-4767-b804-275bb45bc5e4'	System	26 Jan 2021 00:59:54
User entered 'No (N)'	System	26 Jan 2021 00:59:54

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-25T18:59:48', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3b02b53c-eea9-4767-b804-275bb45bc5e4' User entered 'No (N)'	System	26 Jan 2021 00:59:54
	System	26 Jan 2021 00:59:54

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-01-25T18:59:51', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3b02b53c-eea9-4767-b804-275bb45bc5e4' User entered '25 Jan 2021 18:59:51'	System	26 Jan 2021 00:59:54

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-02T15:50:23', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '7768b855-11cf-483d-a493-d92ce3420d72' User entered 'No (N)'	System	02 Feb 2021 21:50:30
	System	02 Feb 2021 21:50:30

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-02T15:50:20', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '7768b855-11cf-483d-a493-d92ce3420d72' User entered 'No (N)'	System	02 Feb 2021 21:50:30
	System	02 Feb 2021 21:50:30

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-02T15:50:27', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '7768b855-11cf-483d-a493-d92ce3420d72' User entered '02 Feb 2021 15:50:27'	System	02 Feb 2021 21:50:30
	System	02 Feb 2021 21:50:30

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-09T12:00:27', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'ab32ff96-217b-4dca-886d-97ffc151e0e4' User entered 'No (N)'	System	16 Feb 2021 21:47:11
	System	16 Feb 2021 21:47:11

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-09T12:00:30', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'ab32ff96-217b-4dca-886d-97ffc151e0e4' User entered 'No (N)'	System	16 Feb 2021 21:47:11
	System	16 Feb 2021 21:47:11

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-09T12:00:33', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'ab32ff96-217b-4dca-886d-97ffc151e0e4' User entered '09 Feb 2021 12:00:33'	System	16 Feb 2021 21:47:11

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-16T15:47:06', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a03c5d1d-b25c-41e1-b7a2-eb8d3a67c3e9' User entered 'No (N)'	System	16 Feb 2021 21:47:14
	System	16 Feb 2021 21:47:14

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-16T15:47:08', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a03c5d1d-b25c-41e1-b7a2-eb8d3a67c3e9' User entered 'No (N)'	System	16 Feb 2021 21:47:14
	System	16 Feb 2021 21:47:14



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-16T15:47:11', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a03c5d1d-b25c-41e1-b7a2-eb8d3a67c3e9' User entered '16 Feb 2021 15:47:11'	System	16 Feb 2021 21:47:14
	System	16 Feb 2021 21:47:14

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-24T00:19:21', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c960300-e4e8-419f-8200-798fca0d4790' User entered 'No (N)'	System	24 Feb 2021 06:19:34
	System	24 Feb 2021 06:19:34

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-24T00:19:28', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c960300-e4e8-419f-8200-798fca0d4790' User entered 'No (N)'	System	24 Feb 2021 06:19:34

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-02-24T00:19:31', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c960300-e4e8-419f-8200-798fca0d4790' User entered '24 Feb 2021 00:19:31'	System	24 Feb 2021 06:19:34
	System	24 Feb 2021 06:19:34

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-03-01T20:45:41', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c8a2796d-df79-4835-8b36-18df46558744' User entered 'No (N)'	System	02 Mar 2021 02:49:21
	System	02 Mar 2021 02:49:21

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-03-01T20:45:44', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c8a2796d-df79-4835-8b36-18df46558744' User entered 'No (N)'	System	02 Mar 2021 02:49:21
	System	02 Mar 2021 02:49:21

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-03-01T20:45:50', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'c8a2796d-df79-4835-8b36-18df46558744' User entered '01 Mar 2021 20:45:50'	System	02 Mar 2021 02:49:21
	System	02 Mar 2021 02:49:21

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-07T10:52:48-06:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c791695-d1f1-410e-9b3a-db87089223be' User entered 'Yes (Y)'	System	08 Mar 2021 00:18:20
	System	08 Mar 2021 00:18:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-07T10:52:52-06:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c791695-d1f1-410e-9b3a-db87089223be'	System	08 Mar 2021 00:18:20
User entered 'No (N)'	System	08 Mar 2021 00:18:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-07T10:53:03-06:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c791695-d1f1-410e-9b3a-db87089223be'	System	08 Mar 2021 00:18:20
User entered 'No (N)'	System	08 Mar 2021 00:18:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-07T10:53:14-06:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c791695-d1f1-410e-9b3a-db87089223be'	System	08 Mar 2021 00:18:20
User entered 'No (N)'	System	08 Mar 2021 00:18:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-07T10:53:49-06:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '2c791695-d1f1-410e-9b3a-db87089223be' User entered '07 Mar 2021 10:53:49'	System	08 Mar 2021 00:18:20
	System	08 Mar 2021 00:18:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-14T15:10:35-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '39f198f6-d03d-4871-9355-94a28a5b1bbc'	System	18 Mar 2021 20:50:37
User entered 'No (N)'	System	18 Mar 2021 20:50:37

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-14T15:10:37-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '39f198f6-d03d-4871-9355-94a28a5b1bbc'	System	18 Mar 2021 20:50:37
User entered 'No (N)'	System	18 Mar 2021 20:50:37

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-14T15:10:40-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '39f198f6-d03d-4871-9355-94a28a5b1bbc' User entered '14 Mar 2021 15:10:40'	System	18 Mar 2021 20:50:37
	System	18 Mar 2021 20:50:37

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-22T12:02:06-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6df0ea66-8988-47ca-b2bd-698ea18abce4'	System	30 Mar 2021 21:55:44
User entered 'No (N)'	System	30 Mar 2021 21:55:44

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-22T12:02:09-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6df0ea66-8988-47ca-b2bd-698ea18abce4'	System	30 Mar 2021 21:55:44
User entered 'No (N)'	System	30 Mar 2021 21:55:44



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-22T12:02:12-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '6df0ea66-8988-47ca-b2bd-698ea18abce4'	System	30 Mar 2021 21:55:44
User entered '22 Mar 2021 12:02:12'	System	30 Mar 2021 21:55:44

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-30T16:55:45-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'd6d78480-af77-4975-9e3f-9bd7cb22c425'	System	30 Mar 2021 21:55:56
User entered 'No (N)'	System	30 Mar 2021 21:55:56

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-30T16:55:49-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'd6d78480-af77-4975-9e3f-9bd7cb22c425'	System	30 Mar 2021 21:55:56
User entered 'No (N)'	System	30 Mar 2021 21:55:56

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-03-30T16:55:53-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'd6d78480-af77-4975-9e3f-9bd7cb22c425'	System	30 Mar 2021 21:55:56
User entered '30 Mar 2021 16:55:53'	System	30 Mar 2021 21:55:56

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-06T15:42:29-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'b89be898-b0e6-477f-a07a-04f9cb130309' User entered 'No (N)'	System	06 Apr 2021 20:42:46
	System	06 Apr 2021 20:42:46

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-06T15:42:39-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'b89be898-b0e6-477f-a07a-04f9cb130309' User entered 'No (N)'	System	06 Apr 2021 20:42:46
	System	06 Apr 2021 20:42:46

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-06T15:42:43-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'b89be898-b0e6-477f-a07a-04f9cb130309'	System	06 Apr 2021 20:42:46
User entered '06 Apr 2021 15:42:43'	System	06 Apr 2021 20:42:46

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-13T16:49:46-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a3ac8d15-8b75-402e-ad7a-73ceaad44688' User entered 'No (N)'	System	13 Apr 2021 21:49:52
	System	13 Apr 2021 21:49:52

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-13T16:49:48-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a3ac8d15-8b75-402e-ad7a-73ceaad44688' User entered 'No (N)'	System	13 Apr 2021 21:49:52
	System	13 Apr 2021 21:49:52

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-13T16:49:50-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'a3ac8d15-8b75-402e-ad7a-73ceaad44688'	System	13 Apr 2021 21:49:52
User entered '13 Apr 2021 16:49:50'	System	13 Apr 2021 21:49:52

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-20T12:39:46-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3ab52a7b-a80d-4fed-95d5-0a4709516beb' User entered 'No (N)'	System	29 Apr 2021 02:16:19
	System	29 Apr 2021 02:16:19

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-20T12:39:48-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3ab52a7b-a80d-4fed-95d5-0a4709516beb' User entered 'No (N)'	System	29 Apr 2021 02:16:19



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-20T12:39:51-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '3ab52a7b-a80d-4fed-95d5-0a4709516beb' User entered '20 Apr 2021 12:39:51'	System	29 Apr 2021 02:16:19

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-27T09:39:53-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'f5569952-6f22-4955-9293-09e40ef474e3' User entered 'No (N)'	System	29 Apr 2021 02:16:20
	System	29 Apr 2021 02:16:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-27T09:39:54-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'f5569952-6f22-4955-9293-09e40ef474e3'	System	29 Apr 2021 02:16:20
User entered 'No (N)'	System	29 Apr 2021 02:16:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-04-27T09:39:57-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'f5569952-6f22-4955-9293-09e40ef474e3' User entered '27 Apr 2021 09:39:57'	System	29 Apr 2021 02:16:20
	System	29 Apr 2021 02:16:20

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-05-03T12:05:49-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '7e5b90e0-fc09-437c-a9ac-13c62b850d49'	System	03 May 2021 17:10:42
User entered 'No (N)'	System	03 May 2021 17:10:42

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[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 (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-05-03T12:05:51-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '7e5b90e0-fc09-437c-a9ac-13c62b850d49'	System	03 May 2021 17:10:42
User entered 'No (N)'	System	03 May 2021 17:10:42

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C6834CD1-E481-4D1A-9A11-64D16A2EA1B1)', Time: '2021-05-03T12:05:53-05:00', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: '7e5b90e0-fc09-437c-a9ac-13c62b850d49'	System	03 May 2021 17:10:42
User entered '03 May 2021 12:05:53'	System	03 May 2021 17:10:42

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:51:13



**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:51:13

**US3862175**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:13
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:51:13

US3862175

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:33:42**

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 21:25:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-03-01T20:45:26', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'b2f2b15b-c183-4c72-af53-8203b3cc7fca'	System	02 Mar 2021 02:48:52
User entered 'No (N)'	System	02 Mar 2021 02:48:52



**US3862175**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:25:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E414ECE7-A332-422D-A438-3EA26C81F375)', Time: '2021-03-01T20:45:33', User OID: 'PatientReportedOutcome (US3862175)', ODM File OID: 'b2f2b15b-c183-4c72-af53-8203b3cc7fca' User entered '01 Mar 2021 20:45:33'	System	02 Mar 2021 02:48:52
	System	02 Mar 2021 02:48:52

US3862175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:57:12

US3862175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered '4 Dec 2020'	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:57:12
	(b) (4)	

US3862175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:57:12

US3862175

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered empty.	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:57:12
	(b) (4)	

US3862175

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:32:58
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:57:16
	(b) (4)	

US3862175

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 02:02:39
User entered 'I'	System	04 Dec 2020 19:57:16

**US3862175**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:32:26



**US3862175**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:32:26

**US3862175**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:32:26

US3862175

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:32:26

US3862175

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:32:48

**US3862175**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User entered 'I'	System	08 Feb 2021 18:32:48

**US3862175**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:37:44

US3862175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 22:38:09
User entered '8 Feb 2021'	Carrie Kibler (b) (4)	08 Feb 2021 19:37:44
	(b) (4)	
	(b) (4), (b) (6)	

US3862175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:37:44



US3862175

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:37:44

US3862175

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:37:54

**US3862175**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User entered 'I'	System	08 Feb 2021 19:37:54

**US3862175**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 22:46:52

US3862175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '05 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 22:46:52

US3862175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 22:46:52

US3862175

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Mar 2021 22:46:52

US3862175

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 22:46:56



**US3862175**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:08:24
User entered 'I'	System	05 Mar 2021 22:46:56

US3862175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:41:48

US3862175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered '08 Apr 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:41:48

US3862175

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:41:48

**US3862175**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered 'VISIT4'	System	08 Apr 2021 18:41:48

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01
	(b) (4)	



**US3862175**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered empty.	System	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

**US3862175**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

**US3862175**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered empty.	System	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered empty.	System	08 Apr 2021 18:42:01



US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered empty.	System	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:42:01

**US3862175**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered empty.	System	08 Apr 2021 18:42:01

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21

US3862175

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21

US3862175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:05

US3862175

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered empty.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:42:05



US3862175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:42:15

US3862175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered '08 Apr 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:42:15

US3862175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered '13:16'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:42:15

US3862175

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered '08 Apr 2021 13:16'	System	08 Apr 2021 18:42:15

US3862175

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Apr 2021 18:42:23

**US3862175**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:21
User entered 'I'	System	08 Apr 2021 18:42:23

US3862175

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

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 16:14:42

US3862175

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

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '05 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 16:14:42



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

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Mar 2021 16:14:42

**US3862175**

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

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'UNBLND_DECIDE'	System	05 Mar 2021 16:14:42

US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 23:31:02
User entered '5 Mar 2021'	Carrie Kibler (b) (4)	05 Mar 2021 19:35:51
	Shetel Anassi (b) (4)	
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '0'	(b) (4) Carrie Kibler (b) (4)	09 Mar 2021 23:31:02
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 08:54:40

US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:35:51

US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Carrie Kibler (b) (4)	09 Mar 2021 23:31:02
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 08:54:40

US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '05 Mar 2021' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 23:31:02
User entered '5 Mar 2021'	Carrie Kibler (b) (4)	05 Mar 2021 19:35:51
	Shetel Anassi (b) (4)	
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:35:51



US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:35:51

US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Not Administered (NA)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:35:51

US3862175

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

Form: Unblinding

Generated On: 12 Aug 2021 13:33:42

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:35:51

**US3862175**

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

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:33:42**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	05 Mar 2021 19:35:51

**US3862175**

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

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'I'	System	05 Mar 2021 19:35:51

US3862175

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered missing code ND - Not Done.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered missing code ND - Not Done.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	05 Mar 2021 19:37:50
DataPoint set to visible.	System	05 Mar 2021 19:35:51



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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered missing code ND - Not Done.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

US3862175

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered missing code ND - Not Done.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	05 Mar 2021 19:37:50
DataPoint set to visible.	System	05 Mar 2021 19:35:51

US3862175

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User accepted default value 'Pre-Dose (PREDOSE)'	Shetel Anassi (b) (4) (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

US3862175

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '11:08'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

**US3862175**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '5 Mar 2021 11:08'	System	05 Mar 2021 19:37:50



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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '097.5' F	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Other (Other)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'temporal'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '066'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'bpm'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '016'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

**US3862175**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'breaths/min'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '120'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50



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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mmHg'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '083'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mmHg'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered missing code ND - Not Done.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered missing code ND - Not Done.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:42

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	05 Mar 2021 19:37:50
DataPoint set to visible.	System	05 Mar 2021 19:35:51

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User accepted default value 'Post-Dose (POSTDOSE)'	Shetel Anassi (b) (4) (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50



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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '13:23'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

**US3862175**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '5 Mar 2021 13:23'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '098.6' F	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Oral (Oral)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50
	(b) (4)	

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

US3862175

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '061'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'bpm'	System	05 Mar 2021 19:37:50



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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '016'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

**US3862175**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'breaths/min'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '131'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mmHg'	System	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '081'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:50

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mmHg'	System	05 Mar 2021 19:37:50

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:59

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:37:59
	(b) (4)	



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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Urine (URINE)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34
	(b) (4)	

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Negative (NEGATIVE)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34
	(b) (4)	

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

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:33:42

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:34

**US3862175**

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

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered empty.	System	05 Mar 2021 19:38:34



US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:56

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:56

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

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)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:56
	(b) (4)	

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'mRNA-1273'	System	05 Mar 2021 19:38:56
DataPoint set to visible.	System	05 Mar 2021 19:35:51

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:56
	(b) (4)	

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '12:52'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:56

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '5 Mar 2021 12:52'	System	05 Mar 2021 19:38:56

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:38:56
	(b) (4)	



US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'ONCE'	System	05 Mar 2021 19:38:56

US3862175

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

Form: Exposure

Generated On: 12 Aug 2021 13:33:42

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 19:38:56

US3862175

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:14

US3862175

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:14
	(b) (4)	

US3862175

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '11:18'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:14

US3862175

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '5 Mar 2021 11:18'	System	05 Mar 2021 19:39:14

US3862175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:49

US3862175

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:33:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:49



**US3862175**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '11:13'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:49

**US3862175**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:33:42**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered '5 Mar 2021 11:13'	System	05 Mar 2021 19:39:49

US3862175

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

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	05 Mar 2021 19:39:54

**US3862175**

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

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:24:01
User entered 'I'	System	05 Mar 2021 19:39:54

**US3862175**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	12 Mar 2021 18:16:12
	(b) (4)	

**US3862175**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '12 Mar 2021'	(b) (4) Thea Marie Cordero	12 Mar 2021 18:16:12
	(b) (4)	

**US3862175**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	12 Mar 2021 18:16:12
	(b) (4)	

**US3862175**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) Thea Marie Cordero	12 Mar 2021 18:16:12
	(b) (4)	



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Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	12 Mar 2021 18:16:17
	(b) (4)	

**US3862175**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User entered 'I'	System	12 Mar 2021 18:16:17

**US3862175**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:42**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:55:00
User entered '1'	System	12 Mar 2021 18:16:17
DataPoint set to visible.	System	12 Mar 2021 18:16:17

**US3862175**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:05
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered '08 Apr 2021'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:05
	(b) (4)	

US3862175

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:05
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:42**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	08 Apr 2021 18:41:05

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	



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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:41:12

US3862175

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:41:12



US3862175

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:41:12

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:41:12

US3862175

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:12
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 18:41:12

**US3862175**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:33:42**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:15
	(b) (4)	

US3862175

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	08 Apr 2021 18:41:15
	(b) (4)	



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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:25
	(b) (4)	

US3862175

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered '08 Apr 2021'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:25
	(b) (4)	

US3862175

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:42

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:25
	(b) (4)	
User entered '13:16'	Carrie Kibler (b) (4)	08 Apr 2021 18:41:25
	(b) (4)	

**US3862175**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:33:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 13:16'	System	08 Apr 2021 18:41:25

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 12 Aug 2021 13:33:42**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:13
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:19:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:06:34
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:01:02

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User closed query 'Per DM CLR: Please review AE and please update to specify whether the AE of Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).		22 Nov 2020 22:25:52
Query 'Per DM CLR: Please review AE and please update to specify whether the AE of Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	18 Nov 2020 20:20:57
User closed query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) of RASH. 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 19:20:35
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash pruritic, LLT: Pruritic rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:16:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 16:16:33
User opened query 'Per DM CLR: Please review AE and please update to specify whether the AE of Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 04:25:36
Data point term sent to Coder	System	06 Nov 2020 20:11:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) of RASH. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'data updated' (Site from DM). Coding entries removed.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:11:04
	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:58
User entered 'RASH [ERYTHEMATOUS AND PRURITIC] of vaccinated arm' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:10:58
User opened query 'Per DM CLR: Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) of RASH. 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)	03 Nov 2020 10:32:16
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash pruritic, LLT: Pruritic rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:38
Data point term sent to Coder	System	09 Oct 2020 19:07:12
User entered 'Rash [erythematous and Pruritic]'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32



US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '13 Sep 2020'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:17:23
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
	(b) (4)	
DataPoint Un-verified.	Sandra Francisco (b) (4)	24 Nov 2020 21:37:49
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Sandra Francisco (b) (4)	24 Nov 2020 21:37:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '2 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	26 Oct 2020 22:17:23
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	09 Oct 2020 19:06:32
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Grade 1/Mild (Grade 1/Mild)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4)	23 Nov 2020 17:11:24
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 19:06:32
	Chanei Henry (b) (4)	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Related (RELATED)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Not Related (NOT RELATED)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User closed query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you. ' (Site from DM).		22 Oct 2020 10:46:33
Query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you. ' answered with 'Completed form' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 19:51:09
User opened query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:56:40
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'I'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

US3862175

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:17:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:42

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:06:32

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 19:06:32



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User closed query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:17:20
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:37:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:37:04
Data point term sent to Coder	System	24 Nov 2020 21:35:34
Query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' answered with 'updated: EDC reflects source' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:35:21
Coding entries removed.	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:35:12
User entered 'ipsilateral axillary lymphadenopathy' reason for change: Per Query Resolution	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:35:12

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:53
DataPoint Verified.		23 Nov 2020 17:11:24
User opened query 'Per DM CLR: Please review if this refers to Lymphadenopathy. If yes, please update AE term to LYMPHADENOPATHY and ensure to provide the specific anatomical location of LYMPHADENOPATHY (e.g., Axillary Lymphadenopathy). If this is Axillary Lymphadenopathy, please specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. Otherwise, confirm that this is not Lymphadenopathy. ' (Site from DM).		03 Nov 2020 10:32:41
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Axillary adenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:11:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 19:11:25
Data point term sent to Coder	System	09 Oct 2020 19:10:16
User entered 'Left axillary adenopathy'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Underarm Gland Swelling or Tenderness on 16 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 09:41:46
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Underarm Gland Swelling or Tenderness on 16 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Investigator verified with subject on OLV1 05MAR2021 that start date was 16SEP2020. EDC and source documents have been updated.' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	05 Mar 2021 18:17:19
DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4)	05 Mar 2021 18:16:48
User entered '16 Sep 2020' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	05 Mar 2021 18:16:48
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom Underarm Gland Swelling or Tenderness on 16 SEP 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:09:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '17 Sep 2020'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User entered empty.	System	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '25 Sep 2020'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User entered empty.	System	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Grade 1/Mild (Grade 1/Mild)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24



US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24



US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Related (RELATED)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Not Related (NOT RELATED)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User closed query 'Per CDM Re-Query: Site response noted; however, per page 51 of CCGs v5.0, Not Applicable is ONLY to be recorded when the AE is Before Dose 1, After Dose 2 or during an IP interruption. Please review if this field can be updated. Else clarify. Thank you.' (Site from DM). User signature succeeded.	(b) (4)	16 Apr 2021 13:04:11
	Hana El Sahly (b) (4)	09 Apr 2021 18:37:20
	(b) (4)	
Query 'Per CDM Re-Query: Site response noted; however, per page 51 of CCGs v5.0, Not Applicable is ONLY to be recorded when the AE is Before Dose 1, After Dose 2 or during an IP interruption. Please review if this field can be updated. Else clarify. Thank you.' answered with 'Data corrected' (Site from DM).	Shetel Anassi (b) (4)	01 Apr 2021 17:36:43
	(b) (4)	
Signature has been broken.	Shetel Anassi (b) (4)	01 Apr 2021 17:36:08
	(b) (4)	
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Shetel Anassi (b) (4)	01 Apr 2021 17:36:08
	(b) (4)	
User opened query 'Per CDM Re-Query: Site response noted; however, per page 51 of CCGs v5.0, Not Applicable is ONLY to be recorded when the AE is Before Dose 1, After Dose 2 or during an IP interruption. Please review if this field can be updated. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:23:22
User closed query 'Per CDM: Exposure Visit 2 Day 29 is 09 Oct 2020. AE#2 has a start date of 16 Sept 2020. Per page 51 of CCGs v5.0, "action taken with investigational product" should be recorded as "Not Applicable" ONLY IF an AE starts after dose 2 or during dose interruption. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:21:04
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per CDM: Exposure Visit 2 Day 29 is 09 Oct 2020. AE#2 has a start date of 16 Sept 2020. Per page 51 of CCGs v5.0, "action taken with investigational product" should be recorded as "Not Applicable" ONLY IF an AE starts after dose 2 or during dose interruption. Please review and reconcile. Thank you. ' answered with 'VISIT 1 OCCURED ON 11 SEPT 2021. PARTICIPANT HAD IPSILATERAL LYMPHADENOPATHY POST VACCINATION AFTER THE FIRST DOSE, HENCE, AE # 02 WAS CREATED AFTER THE PARTICIPANT HAD THE FIRST DOSE' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 23:20:13
User opened query 'Per CDM: Exposure Visit 2 Day 29 is 09 Oct 2020. AE#2 has a start date of 16 Sept 2020. Per page 51 of CCGs v5.0, "action taken with investigational product" should be recorded as "Not Applicable" ONLY IF an AE starts after dose 2 or during dose interruption. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 14:21:28
User closed query 'Per CDM Re-Query: Site response noted; however, only one AE should be recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	07 Dec 2020 09:53:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Chanei Henry (b) (4)	04 Dec 2020 19:08:14
Query 'Per CDM Re-Query: Site response noted; however, only one AE should be recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' answered with 'All other options listed in the drop down does not apply.' (Site from DM).	Chanei Henry (b) (4)	04 Dec 2020 19:08:14
	Chanei Henry (b) (4)	04 Dec 2020 19:07:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM Re-Query: Site response noted; however, only one AE should be recorded with IP Withdrawal. Please only record the AE the PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:19:18
User closed query 'Per CDM Re-query: "Action taken with IP" is recorded as IP withdrawn in more than one AE record. Please consider to update IP withdrawn in only one AE record.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:18:15
Query 'Per CDM Re-query: "Action taken with IP" is recorded as IP withdrawn in more than one AE record. Please consider to update IP withdrawn in only one AE record.' answered with 'IP withdrawn due to AE #01 and AE #02' (Site from DM). DataPoint Verified.	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:35:43
User opened query 'Per CDM Re-query: "Action taken with IP" is recorded as IP withdrawn in more than one AE record. Please consider to update IP withdrawn in only one AE record.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User closed query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:38:01
Query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you.' answered with 'Completed form' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	22 Oct 2020 10:46:39
User opened query 'Per CDM: "Action taken with investigational product" is recorded as "Investigational Product Withdrawn"; however, "Dose discontinuation" form is not filled in. Please review and update all related eCRF forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 19:51:19
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Chanei Henry (b) (4) (b) (4)	14 Oct 2020 13:57:05

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'l'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:09:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User entered '0'	System	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37
User entered '0'	System	09 Oct 2020 19:09:24

US3862175

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:33:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:37

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:14:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:14:22
Data point term sent to Coder	System	06 Nov 2020 20:13:24
User entered 'exacerbation of seasonal allergies'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '27 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User entered empty.	System	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Un-verified.	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:51:07
User entered 'No (N)' reason for change: New Information	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:51:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Un-verified.	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:51:07
User entered '20 Nov 2020' reason for change: New Information	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:51:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User entered empty.	System	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:40:13
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' answered with 'UPDATED' (Site from DM).	Thea Marie Cordero (b) (4)	09 Feb 2021 20:02:13
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	09 Feb 2021 20:02:07
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	09 Feb 2021 20:02:07
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 02:14:13
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Grade 1/Mild (Grade 1/Mild)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:12:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Nov 2020 20:12:35
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:35
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:12:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24



US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Not Related (NOT RELATED)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Not Related (NOT RELATED)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User closed query 'Per CDM: "Action taken with IP" is recorded as IP withdrawn in more than one AE record. Please consider to update IP withdrawn in only one AE record.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 14:18:08
Query 'Per CDM: "Action taken with IP" is recorded as IP withdrawn in more than one AE record. Please consider to update IP withdrawn in only one AE record.' answered with 'updated: EDC matches source' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:42:54
DataPoint Un-verified.	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:42:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:42:37
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:35:41
DataPoint Un-verified.		23 Nov 2020 17:14:00
DataPoint Verified.		23 Nov 2020 17:11:24
User opened query 'Per CDM: "Action taken with IP" is recorded as IP withdrawn in more than one AE record. Please consider to update IP withdrawn in only one AE record.' (Site from DM).		20 Nov 2020 09:38:32
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:13:01
User entered 'Not Applicable (NOT APPLICABLE)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

US3862175

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'l'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:33:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Un-verified.	Chanei Henry (b) (4)	04 Dec 2020 19:51:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Chanei Henry (b) (4)	04 Dec 2020 19:51:07
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Carrie Kibler (b) (4)	06 Nov 2020 20:12:24
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:11:24
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:12:24



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User entered '0'	System	06 Nov 2020 20:12:35

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41
User entered '0'	System	06 Nov 2020 20:12:24

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:41

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries by physical agents, HLT: Conditions caused by cold, PT: Chillblains, LLT: Chilblains - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 22:09:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 22:09:38
Data point term sent to Coder	System	09 Feb 2021 19:55:02
User entered 'CHILBLAINS ON INDEX, MIDDLE AND RING FINGERS OF RIGHT HAND'	Thea Marie Cordero	09 Feb 2021 19:54:40

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'Yes (Y)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'No (N)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'No (N)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '10 Jan 2021'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User entered empty.	System	09 Feb 2021 19:54:40

US3862175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:20
Signature has been broken.	(b) (4)	08 Apr 2021 18:44:37
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	08 Apr 2021 18:44:37
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:49
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	09 Feb 2021 19:54:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:20
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)	08 Apr 2021 18:44:44
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 Apr 2021 18:44:44
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 Apr 2021 18:44:37
Signature has been broken.	Carrie Kibler (b) (4)	08 Apr 2021 18:44:37
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 18:44:37
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:49
User entered empty.	Thea Marie Cordero (b) (4)	09 Feb 2021 19:54:40

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User entered empty.	System	09 Feb 2021 19:54:40

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'No (N)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

US3862175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

US3862175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

US3862175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'Not Related (NOT RELATED)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

US3862175

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered 'I'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	



**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered '0'	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:20
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:44:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:44:44
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero (b) (4)	09 Feb 2021 19:54:40

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:49
User entered empty.	(b) (4)	09 Feb 2021 19:54:40
	Thea Marie Cordero	
	(b) (4)	

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User entered '0'	System	09 Feb 2021 19:54:40

**US3862175**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46
User entered '1'	System	09 Feb 2021 19:54:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:33:42

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:37:46

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:33:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:22:10
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:14:56



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 17:26:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 22:16:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 22:16:58
Data point term sent to Coder	System	14 Sep 2020 22:15:55
User entered 'Mulitvitamin'	Trent Davis (b) (4)	14 Sep 2020 22:15:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Prophylaxis for general health'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'I'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'tablet (TABLET)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'every week (QS)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54



**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'un UNK 2010' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	09 Oct 2020 19:11:54
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '0' reason for change: New Information	Chanei Henry (b) (4)	09 Oct 2020 19:11:54
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	14 Sep 2020 22:15:54
	(b) (4)	

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:15:54

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 22:15:54



**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 22:15:54

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	14 Sep 2020 22:15:54

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: LO LOESTRIN FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 12:51:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 12:51:41
Data point term sent to Coder	System	14 Sep 2020 22:17:59
User entered 'lo loestrin'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'endometriosis'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'I'	Trent Davis (b) (4)	14 Sep 2020 22:17:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'tablet (TABLET)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'un UNK 2011'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 22:17:14

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 22:17:14

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 22:17:14

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 22:17:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:17:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:17:27
Data point term sent to Coder	System	26 Oct 2020 22:16:18
User entered 'benadryl'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'seasonal allergies'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '7.5' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 22:09:03
User entered '12.5'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'mg (mg)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'once daily (QD)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '19 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '0'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08



**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '24 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 22:16:08

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User entered '1'	System	26 Oct 2020 22:16:08

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User entered '1'	System	26 Oct 2020 22:16:08

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:56
User entered '804 (804)'	System	26 Oct 2020 22:16:08

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:17:36
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 20:17:36
Data point term sent to Coder	System	06 Nov 2020 20:16:34
User entered 'claritin'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'seasonal allergies'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '10'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'mg (mg)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'once daily (QD)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '1 Nov 2020'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Un-verified.	(b) (4)	
	Chanei Henry (b) (4)	04 Dec 2020 19:51:44
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Chanei Henry (b) (4)	04 Dec 2020 19:51:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	06 Nov 2020 20:15:38
	(b) (4)	

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Un-verified.	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:51:44
User entered '20 Nov 2020' reason for change: New Information	(b) (4) Chanei Henry (b) (4)	04 Dec 2020 19:51:44
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4)	06 Nov 2020 20:15:38
	(b) (4)	

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:15:38

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User entered '1'	System	06 Nov 2020 20:15:38

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User entered '1'	System	06 Nov 2020 20:15:38

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:19:59
User entered '804 (804)'	System	06 Nov 2020 20:15:38



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:17:36
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 20:17:36
Data point term sent to Coder	System	06 Nov 2020 20:16:34
User entered 'influenza vaccine'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'influenza prevention'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '0.5'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'mL (mL)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'once (ONCE)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered empty.	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '17 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '0'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered '17 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 17:26:36
User entered 'No (N)'	Carrie Kibler (b) (4)	06 Nov 2020 20:16:15
	(b) (4)	

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User entered empty.	System	06 Nov 2020 20:16:15



US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User entered empty.	System	06 Nov 2020 20:16:15

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:04
User entered empty.	System	06 Nov 2020 20:16:15

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:48:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:48:45
Data point term sent to Coder	System	08 Feb 2021 19:52:02
User entered 'Prednisone'	(b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Chilbains on index, middle, ring fingers of right hand'	(b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '20' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:08:38
User entered '15'		08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 19:51:06



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'once daily (QD)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:14:25
User entered 'other (OTHER)'		08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User closed query 'Per DM CLR: Please record tapering doses in separate entries. Update as appropriate. ' (Site from DM).		16 Apr 2021 17:32:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
	(b) (4)	
User closed query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	24 Mar 2021 23:14:25
Query 'Per DM CLR: Please record tapering doses in separate entries. Update as appropriate. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 23:08:49
User opened query 'Frequency is Other, however Other, specify is missing. Please provide.' (Site from System).	System	24 Mar 2021 23:08:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 23:08:38
User opened query 'Per DM CLR: Please record tapering doses in separate entries. Update as appropriate. ' (Site from DM).		06 Mar 2021 15:39:09
User entered 'Titrate from 5 tabs to 1 per day'		08 Feb 2021 19:51:06

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:42**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:51:06

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '19 Feb 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:08:38
User entered '06 Feb 2021'		08 Feb 2021 19:51:06



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 19:51:06

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User entered '1'	System	24 Mar 2021 23:14:25
User entered empty.	System	08 Feb 2021 19:51:06

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User entered '1'	System	24 Mar 2021 23:14:25
User entered empty.	System	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:08
User entered '804 (804)'	System	24 Mar 2021 23:14:25
User entered empty.	System	08 Feb 2021 19:51:06

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 12:58:16
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:24:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 12:24:50
Data point term sent to Coder	System	09 Mar 2021 23:33:41
Query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' answered with 'ADDED' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	09 Mar 2021 23:33:20
Coding entries removed.	Carrie Kibler (b) (4) (b) (4)	09 Mar 2021 23:33:15
User entered 'CLOBETASOL 0.05%' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	09 Mar 2021 23:33:15
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 05:05:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 05:05:14

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name as there are multiple drug strengths for this medication. Please update as appropriate.' (Site from DM). Data point term sent to Coder Coding entries removed.	(b) (4), (b) (6) (b) (4) System Sandra Francisco (b) (4) (b) (4) Coder Import (b) (4) (b) (4)	06 Mar 2021 15:39:47  05 Mar 2021 16:14:41 05 Mar 2021 16:14:17  09 Feb 2021 00:54:39
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.		
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 00:54:39
Data point term sent to Coder User entered 'Clobetasol'	System (b) (4), (b) (6)	08 Feb 2021 19:54:03 08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Chilbains on index, middle, ring fingers of right hand'	(b) (4), (b) (6)	08 Feb 2021 19:53:13



**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:42**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'application'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:42**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Mar 2021 16:14:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Mar 2021 16:14:17
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Sandra Francisco (b) (4)	05 Mar 2021 16:14:17
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Feb 2021 19:53:13
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:20
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:46:28
User entered 'No (N)' reason for change: New Information	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:46:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:37:20
Signature has been broken.	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:46:28
User entered '01 Mar 2021' reason for change: New Information	(b) (4) Carrie Kibler (b) (4)	08 Apr 2021 18:46:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:53:13

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4), (b) (6)	08 Feb 2021 19:53:13

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User entered empty.	System	08 Feb 2021 19:53:13

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User entered empty.	System	08 Feb 2021 19:53:13

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:12
User entered empty.	System	08 Feb 2021 19:53:13

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 23:12:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	24 Mar 2021 23:12:55
Data point term sent to Coder	System	24 Mar 2021 23:11:40
User entered 'PREDNISONE'	(b) (4), (b) (6)	24 Mar 2021 23:10:57



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'CHILBAINS ON INDEX, MIDDLE, RING FINGERS OF RIGHT HAND'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '15'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:10:57

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User entered '1'	System	24 Mar 2021 23:10:57

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User entered '1'	System	24 Mar 2021 23:10:57



**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:15
User entered '804 (804)'	System	24 Mar 2021 23:10:57

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 23:28:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	24 Mar 2021 23:28:41
Data point term sent to Coder	System	24 Mar 2021 23:12:41
User entered 'PREDNISONE'	(b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'CHILBAINS ON INDEX, MIDDLE, RING FINGERS OF RIGHT HAND'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '10'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 23:12:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 23:12:42
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 23:12:42
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 23:12:32
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:33:42**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:33:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:12:32



**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:33:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User entered '1'	System	24 Mar 2021 23:12:32

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User entered '1'	System	24 Mar 2021 23:12:32

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:20
User entered '804 (804)'	System	24 Mar 2021 23:12:32

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 23:14:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 23:14:41
Data point term sent to Coder	System	24 Mar 2021 23:13:42
User entered 'PREDNISONE'	(b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'CHILBAINS ON INDEX, MIDDLE, RING FINGERS OF RIGHT HAND'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '5'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 23:13:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 23:13:53
User entered 'once daily (QD)' reason for change:	(b) (4), (b) (6)	24 Mar 2021 23:13:53
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 23:13:41
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

**US3862175**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:33:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41



US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User entered '1'	System	24 Mar 2021 23:13:53
User entered empty.	System	24 Mar 2021 23:13:41

US3862175

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:33:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User entered '1'	System	24 Mar 2021 23:13:53
User entered empty.	System	24 Mar 2021 23:13:41

US3862175

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:33:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:20:25
User entered '804 (804)'	System	24 Mar 2021 23:13:53
User entered empty.	System	24 Mar 2021 23:13:41

US3862175

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:33:42**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	25 Mar 2021 22:56:40
	(b) (4)	

US3862175

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:33:42

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:20:35
User closed query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).		03 Nov 2020 14:11:41
Query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' answered with 'updated' (Site from DM).	Chanei Henry (b) (4) (b) (4)	30 Oct 2020 17:19:54
User entered '11 Sep 2020' reason for change: Per Query Resolution	Chanei Henry (b) (4) (b) (4)	30 Oct 2020 17:19:48
User opened query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:48:48
User entered '9 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 19:50:18

US3862175

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:33:42

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:32:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:20:37
User entered 'AE (specify) (ADVERSE EVENT)'	Carrie Kibler (b) (4) (b) (4)	19 Oct 2020 19:50:18



US3862175

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:33:42

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 05:32:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:32:34
User entered 'AE #1 and #2' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	24 Nov 2020 21:43:07
User closed query 'Please just record the AE log line, ie., AE #1. Please do not include any other text.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:53:55
User closed query 'Per CDM Re-Query: Site response noted. Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:21:08
Query 'Please just record the AE log line, ie., AE #1. Please do not include any other text.' answered with 'Updated' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 19:14:46
Query 'Per CDM Re-Query: Site response noted. Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 19:14:41
User entered 'AE #1' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	23 Nov 2020 19:14:36
User opened query 'Please just record the AE log line, ie., AE #1. Please do not include any other text.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:20:20
User opened query 'Per CDM Re-Query: Site response noted. Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:04:47
Query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' canceled (Site from DM).		20 Nov 2020 15:04:29
User opened query 'Per CDM: Per page 44 of CCGs v2.0, record the exact AE log line and do NOT record any AE term text. Please review and reconcile. Thank you.' (Site from DM).		20 Nov 2020 15:04:27

US3862175

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:33:42

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 09:38:06
Query 'Per CDM: Please record AE record number instead of details ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4)	18 Nov 2020 20:59:50
User entered 'AE (#1) SUBJECT DEVELOPED AN ERYTHEMATOUS PATCH AT THE SITE OF THE INJECTION AFTER THE 1ST DOSE BY 13SEP2020. ALSO, REPORTED AXILLARY ADENOPATHY.' reason for change: Data Entry Error	Shetel Anassi (b) (4)	18 Nov 2020 20:59:46
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:56:10
User entered 'Subject developed an erythematous patch at the site of the injection after the 1st dose by 13sep2020. Also, reported axillary adenopathy.'	Carrie Kibler (b) (4)	19 Oct 2020 19:50:18