

US3742477 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:23:32

All time stamps listed in this document are displayed in GMT

US3742477

**Form: Participant Creation**

**Data signed:** (b) (4) 23 Feb 2021 18:27:47

**Generated On:** 12 Aug 2021 13:23:32

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[Participant ID](#)

US3742477

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

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US3742477

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Date of Birth (MMM yyyy)	(b) (6) 1971
Age	49
Age Units	YEARS
Age (Derived)	49
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	True

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:58:44

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:58:44

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Condition	ASTHMA MODERATE
Start date (dd MMM yyyy)	UN APR 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN DEC 2016
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)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	6 MAR 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	6 MAR 1998
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1998
Start Year (derived)	1998
Stop Month and Year (derived)	MAR 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Condition	CYST REMOVAL(LEFT HAND)
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN DEC 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2016
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	DEC 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:16
Height (xxx.x)	61.0 in
Weight (xxx.x)	230.1 lb
BMI (xxx.x)	43.56792 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	064 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

28 SEP 2020

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*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) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*) 28 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*) 6 MAR 1998

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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:58:44

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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**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:58:44

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

What was the date of randomization? (dd MMM yyyy) 01 OCT 2020

What was the participant's randomization number? 146701

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/m<sup>2</sup>) Yes ☒   
 No ☐

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Height	61.5 in
Weight	231.2 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Height	61.5 in
Weight	231.2 lb
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)	01 OCT 2020
Time of assessment (00:00-23:59)	12:13 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 12:13
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 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)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Height	61.5 in
Weight	231.2 lb
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)	01 OCT 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:36
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 13:04 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 13:04

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	12:29 (24 HR)
Collection date and time (derived)	01 OCT 2020 12:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Collection date (dd MMM yyyy)			01 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:34	01 OCT 2020 12:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**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

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

01 OCT 2020 13:41

PC Open Date & Time

01 OCT 2020 13:24

PC Close Date & Time

01 OCT 2020 15:54

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °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	01 OCT 2020 18:42
PC Open Date & Time	01 OCT 2020 16:49
PC Close Date & Time	02 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**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

98.2 °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

02 OCT 2020 18:26

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

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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

96.8 °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

03 OCT 2020 15:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

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**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

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 19:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**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

05 OCT 2020 19:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

06 OCT 2020 22:07

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**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

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 OCT 2020 16:10

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 8

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

08 OCT 2020 19:53

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**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

01 OCT 2020 13:40

PC Open Date & Time

01 OCT 2020 13:24

PC Close Date & Time

01 OCT 2020 15:54

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**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

01 OCT 2020 18:43

PC Open Date & Time

01 OCT 2020 16:49

PC Close Date & Time

02 OCT 2020 11:59



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**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

02 OCT 2020 18:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**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

03 OCT 2020 15:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**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 ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 19:05

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**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

05 OCT 2020 19:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**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

06 OCT 2020 22:08

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**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

07 OCT 2020 16:11

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 13:42
PC Open Date & Time	01 OCT 2020 13:24
PC Close Date & Time	01 OCT 2020 15:54



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 18:43
PC Open Date & Time	01 OCT 2020 16:49
PC Close Date & Time	02 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**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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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 18:28
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 15:51
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

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 ☒

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EAB) (1725)

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 19:06
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

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 ☒

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 19:37
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 22:08
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**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 ☒

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EAB) (1725)

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 16:11
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

08 OCT 2020 19:53

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:32

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time Stamp

09 OCT 2020 19:30

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

---



US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 OCT 2020 19:59

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 8

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 08 OCT 2020 19:54

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 9

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

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 09 OCT 2020 19:30

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:32

<b>TIMEPOINT</b>	DAY 8
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	08 OCT 2020 19:54
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:32

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 19:30
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3742477

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

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

US3742477

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

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	

US3742477

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

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.*

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

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?



US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3742477

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

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

PARTICIPANT IN  
CONVALESCENT PERIOD

If Contact Not Made, please provide Comments

US3742477

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

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

US3742477

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

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



US3742477

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:43

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Apr 2021 16:10:39

Generated On: 12 Aug 2021 13:23:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 13:47
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	081 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

14:20 (24 HR)

Collection date and time (derived)

23 NOV 2020 14:20

US3742477

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:58:44

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 61

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

28 NOV 2020 19:12:56

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 68
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	05 DEC 2020 11:37:38
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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	12 DEC 2020 00:01:35
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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	19 DEC 2020 16:01:00
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 15:43:43
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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	02 JAN 2021 12:07:05
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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

09 JAN 2021 11:58:14

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 08:20:55

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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

24 JAN 2021 19:19:50

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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	30 JAN 2021 13:12:42
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <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	06 FEB 2021 12:48:14
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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

13 FEB 2021 10:41:35

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

<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	20 FEB 2021 11:41:14
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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

27 FEB 2021 19:23:41

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

<b>TIMEPOINT</b>	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	06 MAR 2021 00:02:35
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

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

14 MAR 2021 09:55:43

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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

20 MAR 2021 10:23:23

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 180

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 07:05:22

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

<b>TIMEPOINT</b>	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	05 APR 2021 11:35:53
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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	10 APR 2021 10:53:20
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <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	19 APR 2021 07:52:27
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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

24 APR 2021 20:58:53

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <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	01 MAY 2021 11:30:15
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐ 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 ☐

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐  
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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐  
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 ☐



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	02 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	13 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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04 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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°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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐ 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 ☐



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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

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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐ 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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐  
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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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°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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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°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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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08 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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11 JUN 2022 00:01

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15 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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22 JUN 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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25 JUN 2022 00:01

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29 JUN 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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06 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <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"/>



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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13 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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16 JUL 2022 00:01

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20 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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27 JUL 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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30 JUL 2022 00:01

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐



US3742477

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

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10 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**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 ☐

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>



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

**Form: Safety Follow Up Diary**

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

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07 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

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

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**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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10 SEP 2022 00:01

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14 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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17 SEP 2022 00:01

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21 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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28 SEP 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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01 OCT 2022 00:01

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05 OCT 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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19 OCT 2022 23:59

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US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

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22 OCT 2022 00:01

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26 OCT 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>



**US3742477**

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

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

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

Date and time of submission

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02 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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="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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2022 23:59

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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"/>

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3742477

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 12 Aug 2021 13:23:32**

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		05 MAR 2021 21:38:22

US3742477

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742477

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3742477

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

US3742477

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

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.*

US3742477

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)



US3742477

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Date of Contact	19 OCT 2020
Time of Contact	10:00
Date and Time of Contact (derived)	19 OCT 2020 10:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:27:49

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:27:49

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 18:27:49

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	100.8 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
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Form: Symptom Log (10)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☐  
Moderate ☒  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Date of Visit	19 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	19 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Feb 2021 18:27:48

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Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

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US3742477

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	21 OCT 2020
Day 5	Yes	23 OCT 2020
Day 7	Yes	26 OCT 2020
Day 9	Yes	27 OCT 2020
Day 14	Yes	02 NOV 2020
Day 21	Yes	09 NOV 2020
Day 28	Yes	23 NOV 2020



US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	SICKD1

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:28
Height (xxx.x)	155 cm
Weight (xxx.x)	226.8 lb
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3742477

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 13:47
Height (xxx.x)	62.0 in
Weight (xxx.x)	225.7 lb
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	081 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3742477

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020



US3742477

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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

Visit date (dd MMM yyyy)	25 JAN 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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US3742477

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:53:28

Generated On: 12 Aug 2021 13:23:32

Date of updated informed consent ( <i>dd MMM yyyy</i> )	25 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	25 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3742477

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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

US3742477

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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)	25 JAN 2021
Time of assessment (00:00-23:59)	09:58 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 09:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3742477

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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)	25 JAN 2021
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 10:59
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3742477

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3742477

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 10:29 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 10:29

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

US3742477

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

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

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00-23:59)	09:46 (24 HR)
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Collection date and time (derived)	25 JAN 2021 09:46
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US3742477

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	09:49
Collection Date and Time (derived)	25 JAN 2021 09:49

US3742477

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

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

US3742477

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

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)	25 FEB 2021
Time of assessment (00:00-23:59)	09:38 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 09:38
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

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)	25 FEB 2021
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 10:22
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3742477

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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



US3742477

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

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) 25 FEB 2021

What was the treatment time? (00:00-23:59) 09:51 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 09:51

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

US3742477

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742477

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742477

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

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) \_\_\_\_\_

US3742477

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

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.*

US3742477

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

09:37 (24 HR)

Collection date and time (derived)

30 MAR 2021 09:37



US3742477

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 21:40:20

Generated On: 12 Aug 2021 13:23:32

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID

Adverse event

RHINORRHEA

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)

07 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)

07 OCT 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID

Adverse event

NASAL CONGESTION

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)

7 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)

8 OCT 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 ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID

Adverse event

BILATERAL SHOULDER PAIN

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)

13 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)

26 OCT 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input 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 (4)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID	
Adverse event	LEFT ELBOW PAIN
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 OCT 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)	26 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input 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 (6)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID	USA-US127-2020-MRNA-1273-P30 1000006
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	14 OCT 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)	31 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Form: Adverse Events (6)

Data signed: (b) (4) 07 Apr 2021 21:55:41

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID	
Adverse event	BILATERIAL FOREARM PAIN
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)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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 (8)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID	
Adverse event	LUMP ON RIGHT BREAST
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input 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)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 07 Apr 2021 21:55:41

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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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID

Adverse event

LEFT ELBOW PAIN

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 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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	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 (10)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	7 OCT 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)	9 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 07 Apr 2021 21:55:41

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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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input 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 (11)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

AEID

Adverse event

MUSCLE ACHES

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)

5 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)

8 OCT 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 07 Apr 2021 21:55:41

Generated On: 12 Aug 2021 13:23:32

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

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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) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication K-21 MINERAL SUPPLEMENT

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 2

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

If dose unit is Other, specify TBSP

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 (1)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication	DIETARY PROTEIN SUPPLEMENT
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	PACKET
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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 MAY 2020	
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) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication HERBAL LAXATIVE TEA

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 1

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

If dose unit is Other, specify PACKET

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) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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 AUG 2020	
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)	_____	
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 (4)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication QVAR INHALER

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 80

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) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 APR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 18:27:48

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Name of Medication DICLOFENAC

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS, KNEE PAIN,  
JOINT PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE ACHES

Dose per administration 500

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 (6)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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)		05 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)		07 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication ACETAMINOPHEN+DEXTROME  
THORPHAN+PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication RHINORRHEA AND NASAL  
CONGESTION

Dose per administration 650/20/10

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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)	07 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)		07 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication ACETAMENOPHEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 500

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 (8)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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)		15 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)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 800

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 ☐

PRODUCTION RELEASE (v12.003

422 of 2668

EAB) (1725)

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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)		25 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication THROMBOSIS PREVENTION

Dose per administration 81

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 ☐

PRODUCTION RELEASE (v12.003

424 of 2668

EAB) (1725)

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 18:27:48

Generated On: 12 Aug 2021 13:23:32

	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)	29 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)	01 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"/>

US3742477

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:55:42

Generated On: 12 Aug 2021 13:23:32

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3742477

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 18:27:49

Generated On: 12 Aug 2021 13:23:32

Date of dosing discontinuation (dd MMM yyyy) 23 OCT 2020

Primary reason for dosing discontinuation

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

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

US3742477

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:23:32

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 ☐

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

SAEID	USA-US127-2020-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

SAEID	USA-US127-2020-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/OCT/2020 17:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

SAEID	USA-US127-2020-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

SAEID	USA-US127-2020-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 18:27:50

Generated On: 12 Aug 2021 13:23:32

SAEID	USA-US127-2020-MRNA-1273-P301000006
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/NOV/2020 09:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3742477 (Prod: University of Maryland School of Medicine)

US3742477

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:23:32**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'US3742477'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 16:37:52

US3742477

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:25

US3742477

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 16:37:53

US3742477

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:25

US3742477

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'SCRN'	System	29 Sep 2020 13:53:25



US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered (b) (6) 1971'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 16:42:42

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '49'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'YEARS'	System	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '49'	System	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59



US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:53:59

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:54



US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Sep 2020'	System	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '2020'	System	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:54:54

US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 16:37:53



US3742477

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'I'	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:23:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:11:52

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 16:29:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 16:29:41
Data point term sent to Coder	System	23 Dec 2020 16:28:44
Coding entries removed.	Sherry McCammon (b) (4)	23 Dec 2020 16:28:00
User entered 'ASTHMA moderate' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 16:28:00
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:03
Data point term sent to Coder	System	29 Sep 2020 14:12:57
User entered 'ASTHMA'	(b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN Apr 2017'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:08



US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Apr 2017'	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '2017'	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	29 Sep 2020 14:12:08

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:04
Data point term sent to Coder	System	29 Sep 2020 14:12:58
User entered 'OSTEOARTHRITIS'	(b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN Dec 2016'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:30



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Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Dec 2016'	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '2016'	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	29 Sep 2020 14:12:30

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:03
Data point term sent to Coder	System	29 Sep 2020 14:13:00
User entered 'TUBAL LIGATION'	(b) (4), (b) (6)	29 Sep 2020 14:12:53



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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '6 Mar 1998'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	29 Sep 2020 14:14:19
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	29 Sep 2020 14:12:53
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '6 Mar 1998' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:14:19
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Mar 1998'	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '1998'	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Mar 1998'	System	29 Sep 2020 14:14:19
User entered empty.	System	29 Sep 2020 14:12:53



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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '1998'	System	29 Sep 2020 14:14:19
User entered empty.	System	29 Sep 2020 14:12:53

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cyst removal, LLT: Cyst removal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Sep 2020 14:37:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:37:43
Data point term sent to Coder	System	29 Sep 2020 14:14:03
User entered 'CYST REMOVAL(LEFT HAND)'	(b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Jan 1995'	System	29 Sep 2020 14:13:26



US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Jan 1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '1995'	System	29 Sep 2020 14:13:26

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Sep 2020 14:14:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 14:14:50
Data point term sent to Coder	System	29 Sep 2020 14:14:04
User entered 'LEFT KNEE REPLACEMENT'	(b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN Dec 2016'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN Dec 2016'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:56



US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Dec 2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Dec 2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '2016'	System	29 Sep 2020 14:13:56

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 20:01:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 20:01:22
Data point term sent to Coder	System	31 Oct 2020 20:00:33
User entered 'CONSTIPATION'	(b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'UN Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 19:59:53



US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'Aug 2020'	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '2020'	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	31 Oct 2020 19:59:53

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:09:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Dec 2020 18:09:42
Data point term sent to Coder	System	23 Dec 2020 18:08:44
User entered 'OBESITY'	Sherry McCammon (b) (4)	23 Dec 2020 18:08:11



US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'I'	Sherry McCammon (b) (4)	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	23 Dec 2020 18:08:11



US3742477

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	23 Dec 2020 18:08:11

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '13:16'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '28 Sep 2020 13:16'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '61.0' in	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '230.1' lb	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '43.56792'	System	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30



US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'kg/m2'	System	29 Sep 2020 14:10:48
DataPoint set to visible.	System	29 Sep 2020 13:55:30

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '098.1' F	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '064'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'bpm'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '14'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'breaths/min'	System	29 Sep 2020 14:10:48



US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '119'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '076'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	29 Sep 2020 14:10:48

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32

US3742477

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32

US3742477

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:11:18

US3742477

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:11:18



US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '6 Mar 1998'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40

US3742477

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:08:40



US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36



US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36



US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

**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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'GROVERY STORE SHOPPING'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 14:09:36

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 14:35:19
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:02



US3742477

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'VISIT1'	System	01 Oct 2020 17:34:02

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:42:46

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '146701'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:42:46

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 16:42:46

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 16:26:10
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User closed query 'per CDM: obesity is marked as yes but not recorded on medical history, please clarify or reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:36:59
Query 'per CDM: obesity is marked as yes but not recorded on medical history, please clarify or reconcile' answered with 'Will record in MH' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 16:26:07
User opened query 'per CDM: obesity is marked as yes but not recorded on medical history, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 15:46:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:55:07



US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:55:07

US3742477

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:55:07
DataPoint set to visible.	System	29 Sep 2020 13:54:54

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '61.5' in	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '231.2' lb	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '61.5' in	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '231.2' lb	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03



US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '12:13'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered '01 Oct 2020 12:13'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '86'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'bpm'	System	01 Oct 2020 17:57:03



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'breaths/min'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '113'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '73'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '61.5' in	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '231.2' lb	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03



US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '13:36'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered '01 Oct 2020 13:36'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03



US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '73'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'bpm'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '12'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'breaths/min'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '106'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'mmHg'	System	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Oct 2020 19:05:13
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Not clinically significant' (Site from System).	(b) (4), (b) (6)	01 Oct 2020 18:29:06
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		01 Oct 2020 17:57:03
User entered '57'	(b) (4), (b) (6)	01 Oct 2020 17:57:03

US3742477

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'mmHg'	System	01 Oct 2020 17:57:03



US3742477

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:05

US3742477

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:05

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '13:04'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:50



US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered '1 Oct 2020 13:04'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'ONCE'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 17:34:50

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '12:29'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:24

US3742477

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered '01 Oct 2020 12:29'	System	01 Oct 2020 17:58:24



US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '12:34'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered '01 Oct 2020 12:34'	System	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:44



US3742477

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered empty.	System	01 Oct 2020 17:58:44

US3742477

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:58:48

US3742477

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered '1'	System	01 Oct 2020 17:58:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6' User entered 'Yes (Y)'	System	01 Oct 2020 17:41:35
	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:17', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6' User entered '98.1'	System	01 Oct 2020 17:41:35
	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:22', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6'	System	01 Oct 2020 17:41:35
User entered 'No (N)'	System	01 Oct 2020 17:41:35

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:29', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '58eb2f55-708c-49ee-9a46-a6d04a0ebef6' User entered '01 Oct 2020 13:41'	System	01 Oct 2020 17:41:35
	System	01 Oct 2020 17:41:35



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '01 Oct 2020 15:54'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:23', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered 'Yes (Y)'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered '97.0'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered 'No (N)'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '00b33e06-80d2-49aa-953f-38b01ad2ca1f' User entered '01 Oct 2020 18:42'	System	01 Oct 2020 22:42:52
	System	01 Oct 2020 22:42:52

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 17:34:50



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 2'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:06', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0' User entered 'Yes (Y)'	System	02 Oct 2020 22:26:38
	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0' User entered '98.2'	System	02 Oct 2020 22:26:38
	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:29', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0'	System	02 Oct 2020 22:26:38
User entered 'No (N)'	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bb156bc8-ba47-4d8d-9aca-1b0a80d0daa0' User entered '02 Oct 2020 18:26'	System	02 Oct 2020 22:26:38
	System	02 Oct 2020 22:26:38

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:34:50



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 3'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered 'Yes (Y)'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered '96.8'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered 'No (N)'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:49:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '344761c7-38fa-4196-a18e-009ef1df1bd2'	System	03 Oct 2020 19:49:48
User entered '03 Oct 2020 15:49'	System	03 Oct 2020 19:49:48

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 4'	System	01 Oct 2020 17:34:50



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:37', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20' User entered 'Yes (Y)'	System	04 Oct 2020 23:05:00
	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20' User entered '97.5'	System	04 Oct 2020 23:05:00
	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20' User entered 'No (N)'	System	04 Oct 2020 23:05:00
	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0326af3a-c017-4061-8f27-c68853eddb20' User entered '04 Oct 2020 19:04'	System	04 Oct 2020 23:05:00
	System	04 Oct 2020 23:05:00

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 5'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:12', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5' User entered 'Yes (Y)'	System	05 Oct 2020 23:36:28
	System	05 Oct 2020 23:36:28



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:18', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5' User entered '97.8'	System	05 Oct 2020 23:36:28
	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:21', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5'	System	05 Oct 2020 23:36:28
User entered 'No (N)'	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:24', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '2251ed89-6096-49ca-8d63-347d650012b5' User entered '05 Oct 2020 19:36'	System	05 Oct 2020 23:36:28
	System	05 Oct 2020 23:36:28

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 6'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:06:45', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered 'Yes (Y)'	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:06:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '97.2'	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:08', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf'	System	07 Oct 2020 02:07:44
User entered 'Yes (Y)'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ADDED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:19:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '1'	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:58:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Oct 2020 02:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '1'	System	07 Oct 2020 02:07:44
User entered '1'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ADDED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:20:02
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '1'	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 16:58:59
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Oct 2020 02:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '1'	System	07 Oct 2020 02:07:44
User entered '1'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92dcb4f7-b6fe-4432-962b-488c770b40bf' User entered '06 Oct 2020 22:07'	System	07 Oct 2020 02:07:44
	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 7'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered 'Yes (Y)'	System	07 Oct 2020 20:10:54



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045' User entered '97.9'	System	07 Oct 2020 20:10:54
	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered 'Yes (Y)'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ADDED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 09:21:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	Kaitlin Mason (b) (4)	24 Oct 2020 16:59:17
User entered '1'	(b) (4)	
	System	07 Oct 2020 20:10:54
	System	07 Oct 2020 20:10:54
	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered '0'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9d81c8f3-96c3-420b-ae8d-b6de2f1cf045'	System	07 Oct 2020 20:10:54
User entered '07 Oct 2020 16:10'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	07 Oct 2020 02:07:44
User entered 'Day 8'	System	07 Oct 2020 02:07:44



US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:52:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered 'Yes (Y)'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:52:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003' User entered '98.0'	System	08 Oct 2020 23:53:12
	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered 'No (N)'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:09', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8f8d9869-4fb9-4411-96a7-e2f67ee94003'	System	08 Oct 2020 23:53:12
User entered '08 Oct 2020 19:53'	System	08 Oct 2020 23:53:12

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:37:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c'	System	01 Oct 2020 17:40:24
User entered 'None (1)'	System	01 Oct 2020 17:40:24



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:38:20', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c' User entered 'No (N)'	System	01 Oct 2020 17:40:24
	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:38:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c' User entered 'No (N)'	System	01 Oct 2020 17:40:24
	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:39:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c' User entered 'None (1)'	System	01 Oct 2020 17:40:24
	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:40:19', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5906d7c8-3876-444f-be43-38ba2b490c8c' User entered '01 Oct 2020 13:40'	System	01 Oct 2020 17:40:24
	System	01 Oct 2020 17:40:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '01 Oct 2020 15:54'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:42:57', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'None (1)'	System	01 Oct 2020 22:43:24



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'No (N)'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:03', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845' User entered 'No (N)'	System	01 Oct 2020 22:43:24
	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:13', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845'	System	01 Oct 2020 22:43:24
User entered 'None (1)'	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:19', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7ce202ad-a9e0-49ec-8fbe-bdb85319a845' User entered '01 Oct 2020 18:43'	System	01 Oct 2020 22:43:24
	System	01 Oct 2020 22:43:24

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 2'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:26:53', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 22:27:57



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2' User entered 'No (N)'	System	02 Oct 2020 22:27:57
	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2' User entered 'No (N)'	System	02 Oct 2020 22:27:57
	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:45', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2'	System	02 Oct 2020 22:27:57
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:27:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '176f62ba-c382-4e93-a759-cf3c80715de2' User entered '02 Oct 2020 18:27'	System	02 Oct 2020 22:27:57
	System	02 Oct 2020 22:27:57

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 3'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:03', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 19:50:27



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:11', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'No (N)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:18', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'No (N)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:22', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e7feace4-680c-4bee-bcfb-8609d70e8672'	System	03 Oct 2020 19:50:27
User entered '03 Oct 2020 15:50'	System	03 Oct 2020 19:50:27

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 4'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:04:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered 'None (1)'	System	04 Oct 2020 23:05:37



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570'	System	04 Oct 2020 23:05:37
User entered 'No (N)'	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570' User entered 'No (N)'	System	04 Oct 2020 23:05:37
	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570' User entered 'None (1)'	System	04 Oct 2020 23:05:37
	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:33', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'd5910e0f-e1b0-42ca-8bb7-3a421e875570' User entered '04 Oct 2020 19:05'	System	04 Oct 2020 23:05:37
	System	04 Oct 2020 23:05:37

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 5'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'None (1)'	System	05 Oct 2020 23:36:42



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:31', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'No (N)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:34', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'No (N)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:37', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7'	System	05 Oct 2020 23:36:42
User entered 'None (1)'	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a290502e-3cc2-4d66-b3ac-2f645f7418b7' User entered '05 Oct 2020 19:36'	System	05 Oct 2020 23:36:42
	System	05 Oct 2020 23:36:42

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 6'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41' User entered 'None (1)'	System	07 Oct 2020 02:08:05
	System	07 Oct 2020 02:08:05



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41' User entered 'No (N)'	System	07 Oct 2020 02:08:05
	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:55', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41' User entered 'No (N)'	System	07 Oct 2020 02:08:05
	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:07:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41'	System	07 Oct 2020 02:08:05
User entered 'None (1)'	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:01', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9a2d64d8-5b0c-425e-8668-aae78e9d2c41' User entered '06 Oct 2020 22:08'	System	07 Oct 2020 02:08:05
	System	07 Oct 2020 02:08:05

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 7'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:10:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered 'None (1)'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15



US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:01', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered 'No (N)'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered 'No (N)'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:10', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered 'None (1)'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:13', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a730b0a2-af84-414c-b047-e4cd4000d80f' User entered '07 Oct 2020 16:11'	System	07 Oct 2020 20:11:15
	System	07 Oct 2020 20:11:15

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:48', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:51', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:41:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'None (0)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:42:02', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered 'No (N)'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T13:42:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7f3d71ba-a5ba-4144-a861-9e49cfd3d01a' User entered '01 Oct 2020 13:42'	System	01 Oct 2020 17:42:11
	System	01 Oct 2020 17:42:11

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 17:34:50



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '01 Oct 2020 15:54'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'None (0)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:31', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'None (0)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'None (0)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:38', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'None (0)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'None (0)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'None (0)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered 'No (N)'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-01T18:43:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0cbe73da-e499-4e54-a5e7-31ad42370f43' User entered '01 Oct 2020 18:43'	System	01 Oct 2020 22:43:57
	System	01 Oct 2020 22:43:57

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '01 Oct 2020 16:49'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 2'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'None (0)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'None (0)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:11', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'None (0)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:14', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'None (0)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:17', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'None (0)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:26', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'None (0)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:37', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered 'No (N)'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-02T18:28:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '52902544-5e99-4630-90e8-3afb944e6398' User entered '02 Oct 2020 18:28'	System	02 Oct 2020 22:28:50
	System	02 Oct 2020 22:28:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 3'	System	01 Oct 2020 17:34:50



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:29', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666' User entered 'None (0)'	System	03 Oct 2020 19:51:21
	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:34', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666' User entered 'None (0)'	System	03 Oct 2020 19:51:21
	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666' User entered 'None (0)'	System	03 Oct 2020 19:51:21
	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:50:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666' User entered 'None (0)'	System	03 Oct 2020 19:51:21
	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:02', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666' User entered 'None (0)'	System	03 Oct 2020 19:51:21
	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:16', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered 'No (N)'	System	03 Oct 2020 19:51:21

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-03T15:51:18', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '40518677-387b-48d1-9e8d-d90fcb341666'	System	03 Oct 2020 19:51:21
User entered '03 Oct 2020 15:51'	System	03 Oct 2020 19:51:21



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 4'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:40', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'None (0)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:05:58', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered 'No (N)'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-04T19:06:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '8693abbd-efa0-4f23-aa8d-1ce0ddf2ba0b' User entered '04 Oct 2020 19:06'	System	04 Oct 2020 23:06:01
	System	04 Oct 2020 23:06:01

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 5'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04' User entered 'None (0)'	System	05 Oct 2020 23:37:24
	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:48', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04' User entered 'None (0)'	System	05 Oct 2020 23:37:24
	System	05 Oct 2020 23:37:24



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:36:54', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'Some interference with activity (2)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04' User entered 'None (0)'	System	05 Oct 2020 23:37:24
	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04' User entered 'None (0)'	System	05 Oct 2020 23:37:24
	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:09', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'None (0)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:12', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04'	System	05 Oct 2020 23:37:24
User entered 'No (N)'	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-05T19:37:21', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '9950eb05-4372-44e4-943d-bebd3816ad04' User entered '05 Oct 2020 19:37'	System	05 Oct 2020 23:37:24
	System	05 Oct 2020 23:37:24

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 17:34:50



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 6'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered 'None (0)'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:08', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered 'None (0)'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:21', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d'	System	07 Oct 2020 02:08:47
User entered 'No interference with activity (1)'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered 'None (0)'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:30', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered 'None (0)'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered 'None (0)'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered 'No (N)'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-06T22:08:45', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3f1a68b2-fae6-4434-b755-8f190626a44d' User entered '06 Oct 2020 22:08'	System	07 Oct 2020 02:08:47
	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	01 Oct 2020 17:34:50
User entered 'Day 7'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:20', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9' User entered 'None (0)'	System	07 Oct 2020 20:11:55
	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'Some interference with activity (2)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered 'No interference with activity (1)'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9' User entered 'None (0)'	System	07 Oct 2020 20:11:55
	System	07 Oct 2020 20:11:55



US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:41', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9' User entered 'None (0)'	System	07 Oct 2020 20:11:55
	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:44', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9' User entered 'None (0)'	System	07 Oct 2020 20:11:55
	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9' User entered 'No (N)'	System	07 Oct 2020 20:11:55
	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-07T16:11:52', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '6eb16eff-43f7-4809-a53f-e7be253ebff9'	System	07 Oct 2020 20:11:55
User entered '07 Oct 2020 16:11'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 17:34:50

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	07 Oct 2020 20:11:55
User entered 'Day 8'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92cf819f-0084-49b7-ac54-85f9fe623ed9'	System	08 Oct 2020 23:53:45
User entered 'Some interference with activity (2)'	System	08 Oct 2020 23:53:45



US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:53:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92cf819f-0084-49b7-ac54-85f9fe623ed9' User entered '08 Oct 2020 19:53'	System	08 Oct 2020 23:53:45
	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	07 Oct 2020 20:11:55
User entered 'Day 9'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:22', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'f59dccd3-8ada-4c53-9519-34f87b12becf'	System	09 Oct 2020 23:30:32
User entered 'No interference with activity (1)'	System	09 Oct 2020 23:30:32

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:28', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'f59dccd3-8ada-4c53-9519-34f87b12becf' User entered '09 Oct 2020 19:30'	System	09 Oct 2020 23:30:32
	System	09 Oct 2020 23:30:32

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:11:55



US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	08 Oct 2020 23:53:45
User entered 'Day 10'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-10T19:59:23', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '01fd513b-7572-4cc2-946f-eb5c4acb8d9d' User entered 'None (0)'	System	10 Oct 2020 23:59:29
	System	10 Oct 2020 23:59:29

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-10T19:59:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '01fd513b-7572-4cc2-946f-eb5c4acb8d9d' User entered '10 Oct 2020 19:59'	System	10 Oct 2020 23:59:29
	System	10 Oct 2020 23:59:29

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 23:53:45

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	07 Oct 2020 02:08:47
User entered 'Day 8'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:32

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:24', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '39ead37e-af7d-48ba-9362-e4fb7444e151'	System	08 Oct 2020 23:54:40
User entered 'Some interference with activity (2)'	System	08 Oct 2020 23:54:40

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:36', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '39ead37e-af7d-48ba-9362-e4fb7444e151' User entered '08 Oct 2020 19:54'	System	08 Oct 2020 23:54:40
	System	08 Oct 2020 23:54:40



US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:08:47

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
Data entry locked.	System	07 Oct 2020 20:11:55
User entered 'Day 9'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:32

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:33', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fb1a60ff-b098-46e1-ab2d-c58f300ba37b' User entered 'None (0)'	System	09 Oct 2020 23:30:42
	System	09 Oct 2020 23:30:42

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:41', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fb1a60ff-b098-46e1-ab2d-c58f300ba37b' User entered '09 Oct 2020 19:30'	System	09 Oct 2020 23:30:42
	System	09 Oct 2020 23:30:42

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:57
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:11:55

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	07 Oct 2020 02:07:44
User entered 'Day 8'	System	07 Oct 2020 02:07:44



US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7137ec4b-193e-4119-aae5-455de7d71c69' User entered 'No (N)'	System	08 Oct 2020 23:54:50
	System	08 Oct 2020 23:54:50

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-08T19:54:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7137ec4b-193e-4119-aae5-455de7d71c69' User entered '08 Oct 2020 19:54'	System	08 Oct 2020 23:54:50
	System	08 Oct 2020 23:54:50

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 02:07:44

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
Data entry locked.	System	07 Oct 2020 20:10:54
User entered 'Day 9'	System	07 Oct 2020 20:10:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:32

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)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '890b85d3-a3e3-45f9-9a25-4cd6f76836b0' User entered 'No (N)'	System	09 Oct 2020 23:30:54
	System	09 Oct 2020 23:30:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-10-09T19:30:51', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '890b85d3-a3e3-45f9-9a25-4cd6f76836b0' User entered '09 Oct 2020 19:30'	System	09 Oct 2020 23:30:54
	System	09 Oct 2020 23:30:54

US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 20:10:54



US3742477

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 15:00:46
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 20:10:54

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '09 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:17

US3742477

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:54:28

US3742477

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'I'	System	29 Oct 2020 21:54:28

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:43



US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:43

US3742477

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:55:50

US3742477

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:01:42
User entered 'I'	System	29 Oct 2020 21:55:50

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	05 Nov 2020 19:56:04
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Oct 2020 21:58:19
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:58:19

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:19

US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty; reason for change Data Entry Error	Hassan Haji (b) (4)	05 Nov 2020 19:56:04
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	29 Oct 2020 21:58:19



US3742477

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty; reason for change Data Entry Error	(b) (4)	05 Nov 2020 19:56:04
User entered 'Participant in Convalescent phase'	Hassan Haji (b) (4)	29 Oct 2020 21:58:19
	(b) (4)	
	(b) (4), (b) (6)	

US3742477

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:30

US3742477

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:16:40
User entered 'I'	System	29 Oct 2020 21:58:30

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'VISIT2'	System	29 Oct 2020 21:58:38

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Oct 2020 21:58:51



US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51



US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Oct 2020 21:58:51



US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51



US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:58:51

US3742477

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:57



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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:58:57

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	30 Oct 2020 16:31:07
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	30 Oct 2020 16:31:07
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	29 Oct 2020 21:59:05
User entered empty.	System	29 Oct 2020 21:59:05
	(b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:05



US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:05

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:10

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:19



US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:19

US3742477

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered empty.	System	29 Oct 2020 21:59:19



US3742477

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:59:25

US3742477

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered '1'	System	29 Oct 2020 21:59:25

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Participant in Convalescent period'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:07:34

US3742477

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 22:07:46

US3742477

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'I'	System	29 Oct 2020 22:07:46



US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09

US3742477

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:28:09

US3742477

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	24 Nov 2020 15:29:34
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	24 Nov 2020 15:28:15
	(b) (4)	

US3742477

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered '1'	System	24 Nov 2020 15:29:34
User entered empty.	System	24 Nov 2020 15:28:15

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12



US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12

US3742477

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:30:12

US3742477

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:18

US3742477

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'I'	System	24 Nov 2020 15:30:18

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:30

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:30

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:30

US3742477

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'VISIT3'	System	24 Nov 2020 15:30:30



US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '13:47'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered '23 Nov 2020 13:47'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '098.1' F	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Milagritos Tapia (b) (4)	20 Apr 2021 16:10:39
User closed query 'Per CDM: Visit 3 Day 57 and Convalescence Visit Day 28 are both on 23 Nov 2020. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 09:44:55
Query 'Per CDM: Visit 3 Day 57 and Convalescence Visit Day 28 are both on 23 Nov 2020. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:54:10
Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:53:59
User entered '081' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:53:59
User opened query 'Per CDM: Visit 3 Day 57 and Convalescence Visit Day 28 are both on 23 Nov 2020. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 04:22:20
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	15 Feb 2021 17:58:44
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Nov 2020 16:19:01
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	24 Nov 2020 16:19:01
User entered '78' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 16:19:01
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Nov 2020 15:31:46



US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '016'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46
	(b) (4)	

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'bpm'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '16'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'breaths/min'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '116'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'mmHg'	System	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '070'	Sherry McCammon (b) (4)	24 Nov 2020 15:31:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered 'mmHg'	System	24 Nov 2020 15:31:46



US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09

US3742477

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09

US3742477

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:33:15

US3742477

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:33:15

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '23 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered '14:20'	Sherry McCammon (b) (4)	24 Nov 2020 15:30:46

US3742477

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered '23 Nov 2020 14:20'	System	24 Nov 2020 15:30:46



US3742477

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:58:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:33:36

US3742477

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered '1'	System	24 Nov 2020 15:33:36

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-11-28T19:12:24', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7e6c3b22-0752-480f-8640-62870cb73428'	System	29 Nov 2020 00:12:58
User entered 'No (N)'	System	29 Nov 2020 00:12:58

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-11-28T19:12:34', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7e6c3b22-0752-480f-8640-62870cb73428'	System	29 Nov 2020 00:12:58
User entered 'No (N)'	System	29 Nov 2020 00:12:58

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-11-28T19:12:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7e6c3b22-0752-480f-8640-62870cb73428' User entered '28 Nov 2020 19:12:56'	System	29 Nov 2020 00:12:58
	System	29 Nov 2020 00:12:58

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-05T11:37:23', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '38ae08f2-d8c7-466f-9167-006a6fabf11c' User entered 'No (N)'	System	05 Dec 2020 16:37:41

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-05T11:37:32', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '38ae08f2-d8c7-466f-9167-006a6fabf11c' User entered 'No (N)'	System	05 Dec 2020 16:37:41

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-05T11:37:38', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '38ae08f2-d8c7-466f-9167-006a6fabf11c' User entered '05 Dec 2020 11:37:38'	System	05 Dec 2020 16:37:41
	System	05 Dec 2020 16:37:41

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-12T00:01:19', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '119403d4-a4a2-49ca-927d-6ee0fd437a76'	System	12 Dec 2020 05:02:01
User entered 'No (N)'	System	12 Dec 2020 05:02:01



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-12T00:01:27', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '119403d4-a4a2-49ca-927d-6ee0fd437a76' User entered 'No (N)'	System	12 Dec 2020 05:02:01
	System	12 Dec 2020 05:02:01

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-12T00:01:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '119403d4-a4a2-49ca-927d-6ee0fd437a76' User entered '12 Dec 2020 00:01:35'	System	12 Dec 2020 05:02:01
	System	12 Dec 2020 05:02:01

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-19T16:00:49', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5f8f88d7-a86d-4e9e-8b5b-7ddf8f744010'	System	19 Dec 2020 21:01:06
User entered 'No (N)'	System	19 Dec 2020 21:01:06

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-19T16:00:56', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5f8f88d7-a86d-4e9e-8b5b-7ddf8f744010'	System	19 Dec 2020 21:01:06
User entered 'No (N)'	System	19 Dec 2020 21:01:06

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-19T16:01:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '5f8f88d7-a86d-4e9e-8b5b-7ddf8f744010' User entered '19 Dec 2020 16:01:00'	System	19 Dec 2020 21:01:06
	System	19 Dec 2020 21:01:06



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-26T15:43:06', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76821720-2001-456e-9dce-20a49667ec9c' User entered 'No (N)'	System	26 Dec 2020 20:43:56
	System	26 Dec 2020 20:43:56

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-26T15:43:11', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76821720-2001-456e-9dce-20a49667ec9c' User entered 'Yes (Y)'	System	26 Dec 2020 20:43:56
	System	26 Dec 2020 20:43:56

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-26T15:43:31', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76821720-2001-456e-9dce-20a49667ec9c'	System	26 Dec 2020 20:43:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Dec 2020 20:43:56

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2020-12-26T15:43:43', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76821720-2001-456e-9dce-20a49667ec9c' User entered '26 Dec 2020 15:43:43'	System	26 Dec 2020 20:43:56
	System	26 Dec 2020 20:43:56

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-02T12:06:48', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e2a849f0-4563-4619-a79f-b0a9a528df5b'	System	02 Jan 2021 17:07:08
User entered 'No (N)'	System	02 Jan 2021 17:07:08

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-02T12:07:01', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e2a849f0-4563-4619-a79f-b0a9a528df5b'	System	02 Jan 2021 17:07:08
User entered 'No (N)'	System	02 Jan 2021 17:07:08

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-02T12:07:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e2a849f0-4563-4619-a79f-b0a9a528df5b' User entered '02 Jan 2021 12:07:05'	System	02 Jan 2021 17:07:08
	System	02 Jan 2021 17:07:08

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-09T11:58:02', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '50e95533-33f5-4687-bf25-8e96c9ddb21e' User entered 'No (N)'	System	09 Jan 2021 16:58:18
	System	09 Jan 2021 16:58:18

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-09T11:58:09', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '50e95533-33f5-4687-bf25-8e96c9ddb21e'	System	09 Jan 2021 16:58:18
User entered 'No (N)'	System	09 Jan 2021 16:58:18

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-09T11:58:14', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '50e95533-33f5-4687-bf25-8e96c9ddb21e' User entered '09 Jan 2021 11:58:14'	System	09 Jan 2021 16:58:18
	System	09 Jan 2021 16:58:18

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-16T08:20:39', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76f6648f-daa9-4af0-94f4-d1ded19685bf' User entered 'No (N)'	System	16 Jan 2021 13:20:58
	System	16 Jan 2021 13:20:58

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-16T08:20:47', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76f6648f-daa9-4af0-94f4-d1ded19685bf' User entered 'No (N)'	System	16 Jan 2021 13:20:58
	System	16 Jan 2021 13:20:58



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-16T08:20:55', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '76f6648f-daa9-4af0-94f4-d1ded19685bf' User entered '16 Jan 2021 08:20:55'	System	16 Jan 2021 13:20:58
	System	16 Jan 2021 13:20:58

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-24T19:19:42', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '689a6f86-8d5c-4ca7-9e98-aaab26d64582' User entered 'No (N)'	System	25 Jan 2021 00:19:51

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-24T19:19:46', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '689a6f86-8d5c-4ca7-9e98-aaab26d64582'	System	25 Jan 2021 00:19:51
User entered 'No (N)'	System	25 Jan 2021 00:19:51

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-24T19:19:50', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '689a6f86-8d5c-4ca7-9e98-aaab26d64582' User entered '24 Jan 2021 19:19:50'	System	25 Jan 2021 00:19:51

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-30T13:12:34', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e6a5bd94-b4e5-4177-93e0-51a73498a3a5'	System	30 Jan 2021 18:12:43
User entered 'No (N)'	System	30 Jan 2021 18:12:43

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-30T13:12:38', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e6a5bd94-b4e5-4177-93e0-51a73498a3a5'	System	30 Jan 2021 18:12:43
User entered 'No (N)'	System	30 Jan 2021 18:12:43

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-01-30T13:12:42', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e6a5bd94-b4e5-4177-93e0-51a73498a3a5' User entered '30 Jan 2021 13:12:42'	System	30 Jan 2021 18:12:43
	System	30 Jan 2021 18:12:43

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-06T12:48:07', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92a282fb-aa77-402c-9271-901e3bb87a12' User entered 'No (N)'	System	06 Feb 2021 17:48:19
	System	06 Feb 2021 17:48:19

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-06T12:48:12', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92a282fb-aa77-402c-9271-901e3bb87a12'	System	06 Feb 2021 17:48:19
User entered 'No (N)'	System	06 Feb 2021 17:48:19

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-06T12:48:14', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '92a282fb-aa77-402c-9271-901e3bb87a12' User entered '06 Feb 2021 12:48:14'	System	06 Feb 2021 17:48:19
	System	06 Feb 2021 17:48:19

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-13T10:41:23', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fe3acd11-341d-4d81-86a8-e853a67d6423' User entered 'No (N)'	System	13 Feb 2021 15:41:38

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-13T10:41:25', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fe3acd11-341d-4d81-86a8-e853a67d6423' User entered 'No (N)'	System	13 Feb 2021 15:41:38



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-13T10:41:35', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fe3acd11-341d-4d81-86a8-e853a67d6423' User entered '13 Feb 2021 10:41:35'	System	13 Feb 2021 15:41:38
	System	13 Feb 2021 15:41:38

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-20T11:41:05', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e02b29f3-0f01-42ae-96cb-f40b5bea4fde' User entered 'No (N)'	System	20 Feb 2021 16:41:18
	System	20 Feb 2021 16:41:18

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-20T11:41:12', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e02b29f3-0f01-42ae-96cb-f40b5bea4fde' User entered 'No (N)'	System	20 Feb 2021 16:41:18
	System	20 Feb 2021 16:41:18

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-20T11:41:14', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'e02b29f3-0f01-42ae-96cb-f40b5bea4fde' User entered '20 Feb 2021 11:41:14'	System	20 Feb 2021 16:41:18
	System	20 Feb 2021 16:41:18

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-27T14:23:33-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3c983e37-b264-4350-b600-78c93c6be881'	System	27 Feb 2021 19:23:47
User entered 'No (N)'	System	27 Feb 2021 19:23:47

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-27T14:23:38-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3c983e37-b264-4350-b600-78c93c6be881'	System	27 Feb 2021 19:23:47
User entered 'No (N)'	System	27 Feb 2021 19:23:47

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-02-27T14:23:41-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '3c983e37-b264-4350-b600-78c93c6be881' User entered '27 Feb 2021 19:23:41'	System	27 Feb 2021 19:23:47

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-06T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '91f76791-03d9-4eac-aa91-c85fb9b1f9fb'	System	06 Mar 2021 05:04:44
User entered 'No (N)'	System	06 Mar 2021 05:04:44

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-06T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '91f76791-03d9-4eac-aa91-c85fb9b1f9fb'	System	06 Mar 2021 05:04:44
User entered 'No (N)'	System	06 Mar 2021 05:04:44

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-06T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '91f76791-03d9-4eac-aa91-c85fb9b1f9fb' User entered '06 Mar 2021 00:02:35'	System	06 Mar 2021 05:04:44
	System	06 Mar 2021 05:04:44

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-14T09:55:31-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bca1e44d-30f1-460c-a257-33ddd438adaf'	System	14 Mar 2021 13:55:47
User entered 'No (N)'	System	14 Mar 2021 13:55:47

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-14T09:55:38-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bca1e44d-30f1-460c-a257-33ddd438adaf'	System	14 Mar 2021 13:55:47
User entered 'No (N)'	System	14 Mar 2021 13:55:47



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-14T09:55:43-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bca1e44d-30f1-460c-a257-33ddd438adaf' User entered '14 Mar 2021 09:55:43'	System	14 Mar 2021 13:55:47
	System	14 Mar 2021 13:55:47

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-20T10:23:15-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a16ebdc3-d069-423c-a39b-e9633b793c78'	System	20 Mar 2021 14:23:29
User entered 'No (N)'	System	20 Mar 2021 14:23:29

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-20T10:23:20-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a16ebdc3-d069-423c-a39b-e9633b793c78'	System	20 Mar 2021 14:23:29
User entered 'No (N)'	System	20 Mar 2021 14:23:29

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-20T10:23:23-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'a16ebdc3-d069-423c-a39b-e9633b793c78'	System	20 Mar 2021 14:23:29
User entered '20 Mar 2021 10:23:23'	System	20 Mar 2021 14:23:29

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-29T07:05:17-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0a2e04e1-dbb5-4c61-8419-0513e745c9f2'	System	29 Mar 2021 11:05:24
User entered 'No (N)'	System	29 Mar 2021 11:05:24

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-29T07:05:19-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0a2e04e1-dbb5-4c61-8419-0513e745c9f2'	System	29 Mar 2021 11:05:24
User entered 'No (N)'	System	29 Mar 2021 11:05:24

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-29T07:05:22-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '0a2e04e1-dbb5-4c61-8419-0513e745c9f2' User entered '29 Mar 2021 07:05:22'	System	29 Mar 2021 11:05:24
	System	29 Mar 2021 11:05:24

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-05T11:35:46-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '45d8529d-b60a-4f29-a6c1-d83cebae9ed1'	System	05 Apr 2021 15:36:36
User entered 'No (N)'	System	05 Apr 2021 15:36:36

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-05T11:35:50-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '45d8529d-b60a-4f29-a6c1-d83cebae9ed1'	System	05 Apr 2021 15:36:36
User entered 'No (N)'	System	05 Apr 2021 15:36:36

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-05T11:35:53-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '45d8529d-b60a-4f29-a6c1-d83cebae9ed1'	System	05 Apr 2021 15:36:36
User entered '05 Apr 2021 11:35:53'	System	05 Apr 2021 15:36:36

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-10T10:53:08-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fa9dc191-8f2a-424a-b169-5885b0125b0d'	System	10 Apr 2021 14:53:25
User entered 'No (N)'	System	10 Apr 2021 14:53:25

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-10T10:53:16-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fa9dc191-8f2a-424a-b169-5885b0125b0d'	System	10 Apr 2021 14:53:25
User entered 'No (N)'	System	10 Apr 2021 14:53:25



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-10T10:53:20-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'fa9dc191-8f2a-424a-b169-5885b0125b0d' User entered '10 Apr 2021 10:53:20'	System	10 Apr 2021 14:53:25
	System	10 Apr 2021 14:53:25

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-19T07:52:21-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bf8b992f-76ed-4145-9bb9-afba0f82961'	System	19 Apr 2021 11:52:30
User entered 'No (N)'	System	19 Apr 2021 11:52:30

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-19T07:52:24-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bf8b992f-76ed-4145-9bb9-afba0f82961'	System	19 Apr 2021 11:52:30
User entered 'No (N)'	System	19 Apr 2021 11:52:30

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-19T07:52:27-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: 'bf8b992f-76ed-4145-9bb9-afba0f82961'	System	19 Apr 2021 11:52:30
User entered '19 Apr 2021 07:52:27'	System	19 Apr 2021 11:52:30

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-24T20:58:46-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '59b5bca2-84a6-4111-b436-e8b5b1cc5920'	System	25 Apr 2021 00:58:57
User entered 'No (N)'	System	25 Apr 2021 00:58:57

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-24T20:58:48-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '59b5bca2-84a6-4111-b436-e8b5b1cc5920'	System	25 Apr 2021 00:58:57
User entered 'No (N)'	System	25 Apr 2021 00:58:57

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-04-24T20:58:53-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '59b5bca2-84a6-4111-b436-e8b5b1cc5920'	System	25 Apr 2021 00:58:57
User entered '24 Apr 2021 20:58:53'	System	25 Apr 2021 00:58:57

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-05-01T11:30:10-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '237c2fd6-d621-4613-92b2-63d51486faa6'	System	01 May 2021 15:30:18
User entered 'No (N)'	System	01 May 2021 15:30:18

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

Have you been exposed to someone with 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 (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-05-01T11:30:12-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '237c2fd6-d621-4613-92b2-63d51486faa6'	System	01 May 2021 15:30:18
User entered 'No (N)'	System	01 May 2021 15:30:18

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-05-01T11:30:15-04:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '237c2fd6-d621-4613-92b2-63d51486faa6'	System	01 May 2021 15:30:18
User entered '01 May 2021 11:30:15'	System	01 May 2021 15:30:18

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:02:40



**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:02:40



US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:02:40



US3742477

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:32

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:02:40

US3742477

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:02:40

**US3742477**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:02:40
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:02:40

US3742477

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:23:32**

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)	25 Apr 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-05T21:38:05-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7db723aa-c908-4f2e-b5fe-737b51321301'	System	06 Mar 2021 03:08:25
User entered 'No (N)'	System	06 Mar 2021 03:08:25

US3742477

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:23:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:20:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6D4B696-C6AF-4079-868C-772639E88700)', Time: '2021-03-05T21:38:22-05:00', User OID: 'PatientReportedOutcome (US3742477)', ODM File OID: '7db723aa-c908-4f2e-b5fe-737b51321301' User entered '05 Mar 2021 21:38:22'	System	06 Mar 2021 03:08:25
	System	06 Mar 2021 03:08:25



US3742477

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 16:18:43

US3742477

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '22 Dec 2020'	Sherry McCammon (b) (4)	23 Dec 2020 16:18:43

US3742477

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Dec 2020 16:18:43

US3742477

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:18:43

US3742477

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 16:18:50

US3742477

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:12:09
User entered '1'	System	23 Dec 2020 16:18:50

US3742477

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	27 Jan 2021 13:24:01

US3742477

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '23 Jan 2021'	Sherry McCammon (b) (4)	27 Jan 2021 13:24:01



US3742477

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	27 Jan 2021 13:24:01

US3742477

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	27 Jan 2021 13:24:01

US3742477

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	27 Jan 2021 13:24:18

US3742477

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User entered '1'	System	27 Jan 2021 13:24:18

US3742477

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:36:11

US3742477

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:36:11

US3742477

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:36:11

US3742477

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:36:11



US3742477

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:36:25

US3742477

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User entered 'I'	System	03 Mar 2021 15:36:25

US3742477

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:32

US3742477

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:32

US3742477

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:32

US3742477

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:32

US3742477

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:38:45

US3742477

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:28
User entered 'I'	System	30 Mar 2021 16:38:45



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:32

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered '19 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:32

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered '10:00'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:32

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:39
User entered '19 Oct 2020 10:00'	System	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:32

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:32

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:33:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:46:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 1 (Day 1)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '14 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
User entered '1' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User closed query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-5. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:13:32
Query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-5. If not collected, please consider recording as Not Done.' answered with 'UPDATED' (Site from DM).	Sherry McCammon (b) (4)	13 Jan 2021 21:21:35
User opened query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-5. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:45:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	02 Feb 2021 19:54:32
User entered empty.	System	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 19:17:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 19:17:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:06:12
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:06:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 2 (Day 2)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:08:11

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '15 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
User entered '1' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	02 Feb 2021 19:54:32
User entered empty.	System	23 Oct 2020 18:08:11



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Severe (Severe)' reason for change:	Sherry McCammon (b) (4)	09 Nov 2020 17:59:29
Data Entry Error	(b) (4)	
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4)	23 Oct 2020 18:08:11
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:08:11

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 3 (Day 3)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '16 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
User entered '1' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	02 Feb 2021 19:54:32
User entered empty.	System	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:11:33
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:11:33

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 4 (Day 4)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:13:53



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '17 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
User entered '1' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	02 Feb 2021 19:54:32
User entered empty.	System	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:13:53
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:13:53

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 5 (Day 5)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '18 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User closed query 'Per CDM: Assessment Not Done is not checked however, symptoms are recorded as Not Done or None. If not done please check Assessment Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:20:04
Query 'Per CDM: Assessment Not Done is not checked however, symptoms are recorded as Not Done or None. If not done please check Assessment Not Done.' answered with 'UPDATED' (Site from DM).	Sherry McCammon (b) (4)	13 Jan 2021 21:22:54
DataPoint Un-verified.	(b) (4)	
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Jan 2021 21:22:20
User opened query 'Per CDM: Assessment Not Done is not checked however, symptoms are recorded as Not Done or None. If not done please check Assessment Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 14:43:57
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	02 Feb 2021 19:54:32
User entered empty.	System	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 20:36:04
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Feb 2021 19:54:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered 'None (None)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 18:18:46
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:18:22
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:18:22

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 6 (Day 6)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '19 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:19:44

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:19:44

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:19:44

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	23 Oct 2020 18:19:44



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.6' F	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:19:44

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:48:14
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:19:44
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
User entered 'Day 6 (Day 6)'	(b) (4)	
	Sherry McCammon (b) (4)	27 Oct 2020 18:50:45
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '20 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.2' F	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:50:45

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 8 (Day 8)'	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:58:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 18:58:17
User entered '21 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:58:17
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 18:53:36
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:53:36

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 18:53:36

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '100' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	27 Oct 2020 18:58:17
User entered empty.	System	27 Oct 2020 18:53:36

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '99.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	27 Oct 2020 18:58:17
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 18:53:36
	(b) (4)	

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 9 (Day 9)'	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '22 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '95'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.7' F	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:02:32

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 10 (Day 10)'	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '23 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '97'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	27 Oct 2020 19:06:01



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '100.8' F	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:06:01

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 11 (Day 11)'	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '24 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '100'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '98.2' F	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:08:24

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Day 12 (Day 12)'	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 19:11:12



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '25 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '96'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User entered '%'	System	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered '97.7' F	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Not Done (Not Done)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Mild (Mild)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'Moderate (Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:16
User entered 'None (None)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:11:12

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered '19 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 05:35:08
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'completed' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:50:33
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Oct 2020 17:50:08
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:50:08



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Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered '19 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:50:43
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:08
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

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Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:30:33
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:43
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 17:50:08
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:32

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:51
User entered 'I'	System	23 Oct 2020 17:50:08

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Per CDM: Please clarify what is meant by entered in error. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:19:52
Query 'Per CDM: Please clarify what is meant by entered in error. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:40:49
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:40:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:46:51
User opened query 'Per CDM: Please clarify what is meant by entered in error. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:46:46
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:59:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:59:00
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:59:00
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Per ETRTR: Please complete data entry in this page (page required for confirmed SARS-COV2-positive), thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:03:20
Query 'Per ETRTR: Please complete data entry in this page (page required for confirmed SARS-COV2-positive), thanks.' answered with 'completed' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:40:54
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:40:38
User opened query 'Per ETRTR: Please complete data entry in this page (page required for confirmed SARS-COV2-positive), thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:32:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:46:53
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:59:27
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:58:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:35:12
User closed query 'Per CDM; Please provide a response for 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:43:03
Query 'Per CDM; Please provide a response for 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 19:56:06
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 19:56:00
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 19:56:00
User opened query 'Per CDM; Please provide a response for 'Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 18:15:42
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:46:55
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:59:29
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:58:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21



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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per CDM: If both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' will be recorded as NO, please remove data from 'If Yes to either Did subject require any of the following:' section.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:14:34
Query 'Per CDM: If both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' will be recorded as NO, please remove data from 'If Yes to either Did subject require any of the following:' section.' answered with 'corrected' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	15 Feb 2021 16:59:10
User opened query 'Per CDM: If both 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' and 'Did the subject have Respiratory failure?' will be recorded as NO, please remove data from 'If Yes to either Did subject require any of the following:' section.' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:18:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:40:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:47:00
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:59:44
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:58:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21



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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per CDM: Please provide a response for 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:14:16
Query 'Per CDM: Please provide a response for 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' answered with 'provided' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	15 Feb 2021 16:59:22
DataPoint Un-verified.	Sherry McCammon (b) (4) (b) (4)	15 Feb 2021 16:58:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	15 Feb 2021 16:58:52
User opened query 'Per CDM: Please provide a response for 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 04:17:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 14:47:01
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:59:50
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 17:58:21
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21



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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:27:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Un-verified.	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	15 Feb 2021 16:58:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:40:38
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21



US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User entered empty.	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:40:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:47:06
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 18:00:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Oct 2020 17:58:21
	Sherry McCammon (b) (4)	23 Oct 2020 17:58:21
	(b) (4)	



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Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:16:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:16
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:58:21

US3742477

Folder: Covid-19 Assessment 19 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:23:32

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:17:05
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:23:35
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:52:14

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 3 (Day 3)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '21 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 5 (Day 5)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30



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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '23 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 7 (Day 7)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '26 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 9 (Day 9)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '27 Oct 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 14 (Day 14)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30



US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered '02 Nov 2020'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 21 (Day 21)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:09:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 for Day 21 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 05:21:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 for Day 21 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:10:43
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:10:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:10:38
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 for Day 21 is reported under Illness visit in PPD central lab, however sample details are not recorded in EDC. Please update as appropriate, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:09:33
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:03:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:30
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:09:50
DataPoint Un-verified.	Kaitlin Mason (b) (4)	18 Nov 2020 15:10:38
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	18 Nov 2020 15:10:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:23:32

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User accepted default value 'Day 28 (Day 28)'	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:23:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:58:15
DataPoint Un-verified.	Kaitlin Mason (b) (4)	04 Dec 2020 15:10:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	04 Dec 2020 15:10:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:27:34
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 15:03:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 15:03:30
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30

US3742477

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:56:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:58:15
DataPoint Un-verified.	Kaitlin Mason (b) (4)	04 Dec 2020 15:10:16
User entered '23 Nov 2020' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	04 Dec 2020 15:10:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:27:34
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:03:30



US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:26:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:48:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:40:33
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:23:26
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	System	23 Oct 2020 17:23:18
	Sherry McCammon (b) (4)	23 Oct 2020 17:23:18
	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:02:34
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:26:15
User closed query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 16:02:56
Query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' answered with 'completed' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 15:06:37
User opened query 'Per ETRTR: Please complete data entry in Saliva Collection page, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:21:03
User entered '19 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:40:33
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:23:18
User entered '19 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 12:27:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:26:15
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:40:33
User entered empty; reason for change Data Entry Error	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:23:18
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:11
User entered 'SICKD1'	System	23 Oct 2020 17:40:33
User entered empty.	System	23 Oct 2020 17:23:18
User entered 'SICKD1'	System	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:49:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	23 Oct 2020 17:25:05
User entered empty; reason for change Data Entry Error	System	23 Oct 2020 17:24:56
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '19 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '19 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '12:28' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '12:28'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User entered '19 Oct 2020 12:28'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered '19 Oct 2020 12:28'	System	23 Oct 2020 17:03:46



US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	23 Oct 2020 17:41:39
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	23 Oct 2020 17:41:39
User entered '155' cm reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:41:39
DataPoint set to visible.	System	23 Oct 2020 17:40:33
DataPoint set to invisible.	System	23 Oct 2020 17:23:18
User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	23 Oct 2020 17:03:46
User entered '155' in	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:03:46
DataPoint set to visible.	System	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
DataPoint set to visible.	System	23 Oct 2020 17:40:33
DataPoint set to invisible.	System	23 Oct 2020 17:23:18
User entered '226.8' lb	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
DataPoint set to visible.	(b) (4) System	23 Oct 2020 17:02:34

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '98.6' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '98.6' F	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered 'Oral (Oral)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '78' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '78'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User entered 'bpm'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'bpm'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '17' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '17'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	



US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User entered 'breaths/min'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'breaths/min'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '110' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
User entered '110'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User entered 'mmHg'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'mmHg'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:53
User entered '69' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 17:41:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 17:24:56
	(b) (4)	
User entered '69'	Sherry McCammon (b) (4)	23 Oct 2020 17:03:46
	(b) (4)	

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21
User entered 'mmHg'	System	23 Oct 2020 17:41:39
User entered empty.	System	23 Oct 2020 17:24:56
User entered 'mmHg'	System	23 Oct 2020 17:03:46

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21

US3742477

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:21

US3742477

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:25:09
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:39:47



US3742477

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:25:09
User entered '19 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:39:47

US3742477

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:23:32

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:25:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:40:09

US3742477

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:27:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:25:47
User entered '19 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 17:40:09

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:55:54
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:02:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:55:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:02:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 04:20:22
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:10:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 23NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:22:36
User entered '23 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 09:55:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:02:03
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:55:59
User entered 'SICKD28'	System	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45



US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '23 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '13:47'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User entered '23 Nov 2020 13:47'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '62.0' in	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
DataPoint set to visible.	(b) (4) System	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '225.7' lb	Sherry McCammon (b) (4)	24 Nov 2020 15:51:45
DataPoint set to visible.	(b) (4) System	24 Nov 2020 15:49:43

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '098.1' F	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered empty.	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45



US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '081'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User entered 'bpm'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '16'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User entered 'breaths/min'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '116'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User entered 'mmHg'	System	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:17:30
User entered '70'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:51:45

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10
User entered 'mmHg'	System	24 Nov 2020 15:51:45



US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:10

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:18:05
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:50:22

US3742477

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:18:05
User entered '23 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:50:22

US3742477

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:23:32

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:18:11
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:52:49

US3742477

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:23:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:56:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:18:11
User entered '23 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:52:49

US3742477

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

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:11:37

US3742477

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

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:11:37



US3742477

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

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:11:37

US3742477

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

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 16:11:37

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:53:29
Signature has been broken.	Kaitlin Mason (b) (4)	12 Apr 2021 15:55:51
User entered '25 Jan 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	12 Apr 2021 15:55:51
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '06 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 16:12:53

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	Kaitlin Mason (b) (4)	30 Mar 2021 15:35:07
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:04:02

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:53

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Amendment 6 or later (Amendment 6 or later)'	Kaitlin Mason (b) (4)	30 Mar 2021 15:35:07
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:04:02

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:53

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:53



US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:53

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:13:22
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	25 Jan 2021 16:12:53

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:53

US3742477

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

Form: Unblinding

Generated On: 12 Aug 2021 13:23:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '1'	System	25 Jan 2021 16:12:53

US3742477

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

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:23:32**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'I'	System	25 Jan 2021 16:12:53

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	25 Jan 2021 16:16:29
DataPoint set to visible.	System	25 Jan 2021 16:12:53



US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	25 Jan 2021 16:16:29
DataPoint set to visible.	System	25 Jan 2021 16:12:53

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '09:58'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Jan 2021 09:58'	System	25 Jan 2021 16:16:29



US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '70'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'bpm'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'breaths/min'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '114'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29



US3742477

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '65'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered empty.	System	25 Jan 2021 16:16:29
DataPoint set to visible.	System	25 Jan 2021 16:12:53

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29



US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '10:59'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Jan 2021 10:59'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '65'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'bpm'	System	25 Jan 2021 16:16:29



US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'breaths/min'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '124'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '77'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:16:29

US3742477

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Jan 2021 16:16:29

US3742477

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:13:48

US3742477

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:13:48



US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:14:58

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:14:58

US3742477

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

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:32**

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 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:14:58

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mRNA-1273'	System	25 Jan 2021 16:14:58
DataPoint set to visible.	System	25 Jan 2021 16:12:53

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:14:58

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '10:29'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:14:58

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Jan 2021 10:29'	System	25 Jan 2021 16:14:58

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:14:58



US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'ONCE'	System	25 Jan 2021 16:14:58

US3742477

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

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 16:14:58

US3742477

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:29

US3742477

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:29

US3742477

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '09:46'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:29

US3742477

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Jan 2021 09:46'	System	25 Jan 2021 16:12:29

US3742477

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:40

US3742477

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:23:32**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:40



US3742477

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:23:32**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '09:49'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:12:40

US3742477

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:23:32**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Jan 2021 09:49'	System	25 Jan 2021 16:12:40

US3742477

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 16:15:03

US3742477

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'I'	System	25 Jan 2021 16:15:03

US3742477

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4)	16 Feb 2021 16:09:42
	(b) (4), (b) (6)	

US3742477

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '1 Feb 2021'	(b) (4)	16 Feb 2021 16:09:42
	(b) (4), (b) (6)	

US3742477

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:09:42

US3742477

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4)	16 Feb 2021 16:09:42
	(b) (4), (b) (6)	



US3742477

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4)	16 Feb 2021 16:09:49
	(b) (4), (b) (6)	

US3742477

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User entered 'I'	System	16 Feb 2021 16:09:49

US3742477

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User entered '1'	System	16 Feb 2021 16:09:49
DataPoint set to visible.	System	16 Feb 2021 16:09:49

US3742477

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:49:21

US3742477

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:49:21

US3742477

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[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 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:49:21

US3742477

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'OLD29'	System	25 Feb 2021 15:49:21

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 15:51:02



US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '09:38'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Feb 2021 09:38'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '75'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02



US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'bpm'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'breaths/min'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '105'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '72'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 15:51:02



US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '10:22'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Feb 2021 10:22'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '66'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02



US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'bpm'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'breaths/min'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '113'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '74'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mmHg'	System	25 Feb 2021 15:51:02

US3742477

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:08



US3742477

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:08

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

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 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'mRNA-1273'	System	25 Feb 2021 15:51:43
DataPoint set to visible.	System	16 Feb 2021 16:09:49

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '09:51'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered '25 Feb 2021 09:51'	System	25 Feb 2021 15:51:43



US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'ONCE'	System	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 15:51:43

US3742477

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 15:55:47

US3742477

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:25:32
User entered 'I'	System	25 Feb 2021 15:55:47

US3742477

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4)	15 Mar 2021 15:48:06
	(b) (4), (b) (6)	

US3742477

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 15:27:10
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Protocol Deviation submitted' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 15:49:16
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Mar 2021 15:48:06
User entered '10 Mar 2021'	(b) (4), (b) (6)	15 Mar 2021 15:48:06

US3742477

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:48:06



US3742477

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4)	15 Mar 2021 15:48:06
	(b) (4), (b) (6)	

US3742477

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:49:24

US3742477

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:43:33
User entered 'I'	System	15 Mar 2021 15:49:24

US3742477

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 16:54:13

US3742477

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:13

US3742477

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:32

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:13

**US3742477**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:32**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 16:54:13

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36



US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

**US3742477**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:32**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:54:36



US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 16:54:36

US3742477

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:48

US3742477

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:54:48



US3742477

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 16:55:07

US3742477

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:55:07

US3742477

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '09:37'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 16:55:07

**US3742477**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:37'	System	30 Mar 2021 16:55:07

US3742477

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:23:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:45
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:40:20
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 7; end date: Day 9) and symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 5; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 15:33:07
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 7; end date: Day 9) and symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 5; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	26 Feb 2021 20:26:16
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 7; end date: Day 9) and symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 5; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 14:50:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:19
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26

US3742477

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:30:02
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Symptom lasted less than 48 hours - participant was brought in for illness visit at a later date' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:45:23
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 20:13:06
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:40:13
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' answered with 'nasal congestion is different than rhinorrhea and thus will remain separate ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 17:27:54
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:45:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:34:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Oct 2020 18:34:47
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 18:33:57
User entered 'rhinorrhea'	Hassan Haji (b) (4)	20 Oct 2020 18:33:11
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:15
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 17:29:58
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 17:29:51
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:45:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:20:52
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	06 Nov 2020 16:31:05
User entered '7 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:33:11
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User entered empty.	System	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	06 Nov 2020 16:31:05
User entered '7 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:33:11
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User entered empty.	System	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11



US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'None (NONE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'I'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

US3742477

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:33:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User entered '0'	System	20 Oct 2020 18:33:11



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26
User entered '0'	System	20 Oct 2020 18:33:11

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

**Generated On:** 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:35:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 18:35:34
Data point term sent to Coder	System	20 Oct 2020 18:34:59
User entered 'nasal congestion'	Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:40:27
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 17:30:43
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 17:30:36
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol section 8.3.4. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:43:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 19:20:41
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '7 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User entered empty.	System	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '8 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User entered empty.	System	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

US3742477

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'None (NONE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'I'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User entered '0'	System	20 Oct 2020 18:34:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31
User entered '0'	System	20 Oct 2020 18:34:30

US3742477

**Folder:** Adverse Events

**Form:** Adverse Events (2)

**Generated On:** 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Oct 2020 18:36:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:36:40
Data point term sent to Coder	System	20 Oct 2020 18:36:01
User entered 'bilateral shoulder pain'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '13 Oct 2020'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User entered empty.	System	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 15:00:09
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:52:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:35:59
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 15:00:09
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User entered empty.	System	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:52:10
User entered 'None (NONE)' reason for change: Data Entry Error	System	24 Oct 2020 16:52:10
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User entered empty.	(b) (4)	
	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	24 Oct 2020 16:52:10
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Kaitlin Mason (b) (4)	24 Oct 2020 16:52:10
User entered '0'	(b) (4)	
	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 15:00:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	System	09 Nov 2020 15:00:09
Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 15:00:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:35:59
	Hassan Haji (b) (4)	20 Oct 2020 18:35:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:35:59

US3742477

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User entered '0'	System	24 Oct 2020 16:52:10



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36
User entered '0'	System	24 Oct 2020 16:52:10

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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in elbow - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Oct 2020 18:37:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:37:49
Data point term sent to Coder	System	20 Oct 2020 18:37:05
User entered 'left elbow pain'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '13 Oct 2020'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45



US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User entered empty.	System	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 15:01:53
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Oct 2020 16:54:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 15:01:53
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User entered empty.	System	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

US3742477

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Oct 2020 16:54:42
User entered 'None (NONE)' reason for change: Data Entry Error	System	24 Oct 2020 16:54:42
User opened query 'Data is required. Please complete.' (Site from System).	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User entered empty.	(b) (4)	
	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	24 Oct 2020 16:54:42
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Kaitlin Mason (b) (4)	24 Oct 2020 16:54:42
User entered '0'	(b) (4)	
	System	20 Oct 2020 18:36:45
	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:36:45



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 15:01:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sherry McCammon (b) (4)	09 Nov 2020 15:01:53
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:36:45
User entered empty.	Hassan Haji (b) (4)	20 Oct 2020 18:36:45
	(b) (4)	

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Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:36:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User entered '0'	System	24 Oct 2020 16:54:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41
User entered '0'	System	24 Oct 2020 16:54:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:41

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:00:14
User entered 'USA-US127-2020-mRNA-1273-P301000006'	System	26 Oct 2020 21:00:09
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 21:00:09

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 19:18:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 19:18:20
Data point term sent to Coder	System	29 Dec 2020 19:16:58
Coding entries removed.	(b) (4), (b) (6)	29 Dec 2020 19:16:18
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 19:16:18
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:22
Data point term sent to Coder	System	23 Nov 2020 20:59:26
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:11
' canceled (Site from System).		
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:24:06
' (Site from System).		
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 18:34:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 18:34:41
Data point term sent to Coder	System	23 Oct 2020 18:33:21



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'symptomatic covid-19'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '14 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: The start date of the event is 14 Oct 2020. Did the subject report any symptoms on that day? If yes, please add those symptoms to 134 Oct 2020 symptom log page. If no, please consider updating start date of the event. ' canceled (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:22:36
User opened query 'PV Query: The start date of the event is 14 Oct 2020. Did the subject report any symptoms on that day? If yes, please add those symptoms to 134 Oct 2020 symptom log page. If no, please consider updating start date of the event. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:30:58
User entered empty.	System	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 15:05:44
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 15:05:44
	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved). ' canceled (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 18:22:21
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved). ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:29:16
User entered empty.	System	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 04:58:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'withdrawn due to positive covid19' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:47:18
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	05 Nov 2020 14:45:52
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:45:52
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Oct 2020 13:23:11
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	24 Oct 2020 13:23:11
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 13:23:11
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Oct 2020 18:36:01
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:33:03

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EAB) (1725)

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:30:46
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Medication was taken for symptoms' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 15:05:02
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:47:05
User entered 'I'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:16:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'recovered' (Site from Safety).	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 15:05:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 15:05:44
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:30:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 20:08:50
Query 'Data is required. Please complete.' answered with 'DUE TO SARS COV 2 ' (Site from System).	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 13:23:16
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 18:33:03
User entered empty.	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:33:03

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:28:14
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:07
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).		07 Nov 2020 01:17:05
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. ' (Site from Safety).		07 Nov 2020 01:17:03
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'No additional treatment reported' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:44:56
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. ' answered with 'No report of positive contacts' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:44:20
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' answered with 'participant did not receive second vaccination due to COVID19 illness' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	05 Nov 2020 14:42:47



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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:30:30
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:29:51
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:29:33
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:33:03

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**Folder:** Adverse Events

**Form:** Adverse Events (6)

**Generated On:** 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Oct 2020 18:33:03

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**Folder:** Adverse Events

**Form:** Adverse Events (6)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 18:33:03

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in arm - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Nov 2020 19:04:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 19:04:14
Data point term sent to Coder	System	24 Nov 2020 15:49:19
User entered 'BILATERIAL FOREARM PAIN'	Sherry McCammon (b) (4) (b) (4)	24 Nov 2020 15:48:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '16 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:48:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 15:48:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

US3742477

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 15:48:53
	(b) (4)	

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**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 15:48:53

US3742477

**Folder:** Adverse Events

**Form:** Adverse Events (7)

**Generated On:** 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 15:48:53

US3742477

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please update the condition to confirm if the LUMP was benign or cancerous. Update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 09:42:31
Query 'Per DM CLR: Please update the condition to confirm if the LUMP was benign or cancerous. Update AE eCRF as appropriate. ' answered with 'DUE TO FIRBROTIC CHANGES PER PI' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 19:57:33
User opened query 'Per DM CLR: Please update the condition to confirm if the LUMP was benign or cancerous. Update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 07:11:04
User coded data point as SOC: Reproductive system and breast disorders, HLG: Breast disorders, HLT: Breast disorders NEC, PT: Breast mass, LLT: Breast lump - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:31:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:31:48
Data point term sent to Coder	System	23 Dec 2020 16:17:35
User entered 'LUMP ON RIGHT BREAST'	Sherry McCammon (b) (4) (b) (4)	23 Dec 2020 16:17:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:04:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:04:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 16:17:14
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:04:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:04:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 16:17:14
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '14 Dec 2020'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 16:17:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Dec 2020 16:17:14



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:04:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:04:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 16:17:14
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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**Folder:** Adverse Events

**Form:** Adverse Events (8)

**Generated On:** 12 Aug 2021 13:23:32

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:04:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:04:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 16:17:14
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:04:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:04:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 16:17:14
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 21:04:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 21:04:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 16:17:14
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	23 Dec 2020 21:04:52
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Dec 2020 21:04:52
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Dec 2020 16:17:14
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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**Folder:** Adverse Events

**Form:** Adverse Events (8)

**Generated On:** 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 16:17:14
	(b) (4)	

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**Folder:** Adverse Events

**Form:** Adverse Events (8)

**Generated On:** 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Dec 2020 21:04:52

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**Folder:** Adverse Events

**Form:** Adverse Events (8)

**Generated On:** 12 Aug 2021 13:23:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Dec 2020 21:04:52

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in elbow - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Feb 2021 15:56:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 15:56:52
Data point term sent to Coder	System	27 Jan 2021 13:32:37
User entered 'left elbow pain'	Sherry McCammon (b) (4) (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '16 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User entered empty.	System	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 13:38:48
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	26 Feb 2021 20:19:21
Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	26 Feb 2021 20:18:56
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Feb 2021 20:18:56
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:19:43
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Feb 2021 19:58:44
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	27 Jan 2021 13:31:54



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
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)	
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	26 Feb 2021 20:19:14
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	26 Feb 2021 20:19:14
Signature has been broken.	System	26 Feb 2021 20:18:56
User entered '19 Feb 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	26 Feb 2021 20:18:56
User signature succeeded.	(b) (4)	
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	02 Feb 2021 19:58:44
	System	27 Jan 2021 13:31:54
	Sherry McCammon (b) (4)	27 Jan 2021 13:31:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User entered empty.	System	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Sherry McCammon (b) (4)	27 Jan 2021 13:31:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
Signature has been broken.	Kaitlin Mason (b) (4)	26 Feb 2021 20:19:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Kaitlin Mason (b) (4)	26 Feb 2021 20:19:14
Data Entry Error	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Jan 2021 13:31:54



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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User entered '0'	System	27 Jan 2021 13:31:54

US3742477

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50
User entered '0'	System	27 Jan 2021 13:31:54

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**Folder:** Adverse Events

**Form:** Adverse Events (9)

**Generated On:** 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:50

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 15:42:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 15:42:59
Data point term sent to Coder	System	03 Mar 2021 15:42:26
User entered 'Fatigue'	(b) (4), (b) (6)	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:55:19
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:57:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:57:50
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:10:35
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User entered empty.	System	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User entered empty.	System	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30



US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 15:42:36
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	03 Mar 2021 15:42:36
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 15:41:30
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 15:42:36
User entered 'None (NONE)' reason for change: Data Entry Error	System	03 Mar 2021 15:42:36
	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 15:41:30
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	03 Mar 2021 15:42:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 15:42:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Mar 2021 15:41:30
User entered '0'	(b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30



US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 15:42:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	03 Mar 2021 15:42:36
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 15:41:30
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 15:41:30

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User entered '0'	System	03 Mar 2021 15:41:30

US3742477

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55
User entered '0'	System	03 Mar 2021 15:41:30

US3742477

**Folder:** Adverse Events

**Form:** Adverse Events (10)

**Generated On:** 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:20:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 15:47:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 15:47:59
Data point term sent to Coder	System	03 Mar 2021 15:47:31
User entered 'Muscle aches'	(b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:55:54
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:58:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 16:58:08
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:10:47
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 15:46:47

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User entered empty.	System	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User entered empty.	System	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47



US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47



US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User closed query 'Per DM: Other Action Taken =None, however there is a Concomitant Medication log line #6 recorded that matches this AE during this timeframe. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:02:18
Query 'Per DM: Other Action Taken =None, however there is a Concomitant Medication log line #6 recorded that matches this AE during this timeframe. Please review and update accordingly.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	26 Mar 2021 13:03:30
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Mar 2021 12:59:47
User opened query 'Per DM: Other Action Taken =None, however there is a Concomitant Medication log line #6 recorded that matches this AE during this timeframe. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 19:49:25
User entered '1'	(b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '1' reason for change: Data Entry Error	(b) (4)	26 Mar 2021 12:59:47
User entered '0'	(b) (4)	03 Mar 2021 15:46:47
	(b) (4), (b) (6)	

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:46:47



US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User entered '0'	System	03 Mar 2021 15:46:47

US3742477

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 12 Aug 2021 13:23:32

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00
User entered '0'	System	03 Mar 2021 15:46:47

US3742477

**Folder:** Adverse Events

**Form:** Adverse Events (11)

**Generated On:** 12 Aug 2021 13:23:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:21:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:23:32

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:45
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per ETRTR: Please add medication dosing details for AE "Symptomatic COVID-19", thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 21:09:57
Query 'Per ETRTR: Please add medication dosing details for AE "Symptomatic COVID-19", thanks.' answered with 'completed. please refer to concomitant medication #08' (Site from CRA).	(b) (4), (b) (6)	31 Oct 2020 19:48:00
User opened query 'Per ETRTR: Please add medication dosing details for AE "Symptomatic COVID-19", thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 22:19:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 19:39:21

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, PRODUCT: MINERAL SUPPLEMENTS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Oct 2020 13:38:33
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 Oct 2020 13:38:33
Data point term sent to Coder	System	01 Oct 2020 19:41:30
User entered 'K-21 Mineral Supplement'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:47:09
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 14:43:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 14:43:00
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:34:51
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '2'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'tbsp'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'UN Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:40:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 19:40:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: PROTEIN SUPPLEMENTS, PRODUCT: PROTEIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 05:15:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 05:15:38
Data point term sent to Coder	System	01 Oct 2020 19:42:35
User entered 'Dietary Protein Supplement'	(b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:47:15
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 14:44:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	26 Oct 2020 14:44:16
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 17:34:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 19:42:31



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Supplement'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '1'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'packet'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'UN May 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 19:42:31

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 19:42:31



US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:32

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: HERBAL PREPARATION - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 14:04:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:04:14
User closed query 'Per CDM Re-query: Response is updated, however, the specific herb is not added on the Name of Medication. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:16:42
Query 'Per CDM Re-query: Response is updated, however, the specific herb is not added on the Name of Medication. ' answered with 'ENTERED ' (Site from DM).	Hassan Haji (b) (4) (b) (4)	02 Nov 2020 14:02:14
User opened query 'Per CDM Re-query: Response is updated, however, the specific herb is not added on the Name of Medication. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:43:25
User closed query 'Per DM CLR: Please review Medication and please update to provide the specific herb taken for constipation. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:41:26
Query 'Per DM CLR: Please review Medication and please update to provide the specific herb taken for constipation. Please update as appropriate or provide clarification.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:01:25
User opened query 'Per DM CLR: Please review Medication and please update to provide the specific herb taken for constipation. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:32:23
Data point term sent to Coder	System	01 Oct 2020 19:43:40
User entered 'Herbal Laxative Tea'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 11:41:40
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:01:37
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH record that match this condition. Please update to record the corresponding MH as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:32:38
User entered 'Constipation'	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '1'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:43:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 19:43:42
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:43:42
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 19:43:33
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Packet'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Oct 2020 19:43:51
User entered 'UN Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:43:51
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	01 Oct 2020 19:43:33
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:43:33



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:43:33

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:43:33

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Nov 2020 23:52:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 23:52:48
Data point term sent to Coder Coding entries removed.	System Hassan Haji (b) (4)	02 Nov 2020 14:03:21 02 Nov 2020 14:02:41
User entered 'QVAR INHALER' reason for change: Data Entry Error	Hassan Haji (b) (4)	02 Nov 2020 14:02:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 19:46:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 19:46:57
Data point term sent to Coder User entered 'Qvar'	System (b) (4), (b) (6)	01 Oct 2020 19:45:44 01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Asthma'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '80'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 11:44:24
Query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:03:17
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Oct 2020 20:03:04
User opened query 'Per DM CLR: Please review recorded Unit as this is not the expected unit for this medication or for the recorded dose. Please update the unit as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:32:51
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'UN Apr 2017'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:45:10

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:45:10

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Nov 2020 18:21:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:21:40
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	31 Oct 2020 20:06:33 31 Oct 2020 20:05:57
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:46:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:46:53
Data point term sent to Coder User entered 'Diclofenac'	System (b) (4), (b) (6)	01 Oct 2020 19:46:45 01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 11:45:39
Query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 20:06:10
User entered 'OSTEOARTHRITIS, KNEE PAIN, JOINT PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Oct 2020 20:05:57
User opened query 'Per DM CLR: Please review Indication and please note, there is no corresponding MH or AE record that match this condition. Please update to record the corresponding MH or AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 19:33:31
User entered 'Knee pain, joint pain'	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '50'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 19:46:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 19:46:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 19:46:00
User entered 'UN UNK UNKN' (non-conformant).	(b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:46:00

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 19:46:00

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:37:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Nov 2020 14:37:35
Data point term sent to Coder Coding entries removed.	System Sherry McCammon (b) (4)	09 Nov 2020 14:36:38 09 Nov 2020 14:36:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:27:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 14:27:32
Data point term sent to Coder User entered 'ibuprofen'	System Hassan Haji (b) (4)	20 Oct 2020 18:26:40 20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:26:14



US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of MUSCLE ACHES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 03:35:32
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:56:06
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'did not meet ae reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	29 Jan 2021 17:14:36
Query 'Per DM CLR: Please update the indication to reflect the location and type of MUSCLE ACHES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'in the muscles - generalized' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	29 Jan 2021 17:14:27

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:21:16
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of MUSCLE ACHES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:21:01
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of REACTOGENETIC SYMPTOMS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:13:00
Query 'Per DM CLR: Please update the indication to reflect the location and type of REACTOGENETIC SYMPTOMS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4)	09 Nov 2020 14:36:47
User entered 'muscle aches' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 14:36:34
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of REACTOGENETIC SYMPTOMS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:33:29
User entered 'reactogenetic symptoms'	Hassan Haji (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '500'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'as needed (PRN)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:26:14

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	06 Nov 2020 16:27:25
User entered '5 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:26:14
	(b) (4)	

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	06 Nov 2020 16:27:25
User entered '7 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:26:14
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:43:01
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:11:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:11:26
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:36:31
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:26:14

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User entered empty.	System	20 Oct 2020 18:26:14

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User entered empty.	System	20 Oct 2020 18:26:14



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:43
User entered empty.	System	20 Oct 2020 18:26:14

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEP HRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 07:52:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 07:52:33
Data point term sent to Coder	System	20 Oct 2020 18:30:48
User entered 'acetaminophen+dextromethorphan+phenylephrine'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'rhinorrhea and nasal congestion'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not plus (e.g. 5/325). If so please update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:21:22
' (Site from DM).		
Query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not plus (e.g. 5/325). If so please update eCRF as appropriate.	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 16:19:53
' answered with 'CORRECTED' (Site from DM).		
User entered '650/20/10' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 16:17:56
User opened query 'Per DM CLR: Please review if the dose of this medication could be recorded using slash and not plus (e.g. 5/325). If so please update eCRF as appropriate.	(b) (4), (b) (6)	06 Nov 2020 15:33:18
' (Site from DM).		
User entered '650+20+10'	Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4)	20 Oct 2020 18:30:17

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	06 Nov 2020 16:19:43
User entered '7 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:30:17
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	06 Nov 2020 16:19:43
User entered '7 Oct 2020'	(b) (4)	
	Hassan Haji (b) (4)	20 Oct 2020 18:30:17
	(b) (4)	

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	20 Oct 2020 18:30:17



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User entered empty.	System	20 Oct 2020 18:30:17

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User entered empty.	System	20 Oct 2020 18:30:17

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:44
User entered empty.	System	20 Oct 2020 18:30:17

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:06:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 00:06:39
Data point term sent to Coder	System	09 Nov 2020 14:41:47
Data point term sent to Coder	System	09 Nov 2020 14:40:46
Coding entries removed.	Sherry McCammon (b) (4)	09 Nov 2020 14:39:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:36:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 15:36:04
Data point term sent to Coder	System	30 Oct 2020 13:16:46
User entered 'ACETAMENOPHEN'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:13:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4)	09 Nov 2020 14:40:58
User entered 'symptomatic covid-19' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 14:40:53
User entered 'rhinorrhea and nasal congestion' reason for change: Data Entry Error	Sherry McCammon (b) (4)	09 Nov 2020 14:39:56
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:31:34
User entered 'VIRAL SYNDROME WITH COUGH'	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '500'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'as needed (PRN)'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '15 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 14:41:33
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	



US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	09 Nov 2020 14:41:33
	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 13:16:50
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	30 Oct 2020 13:16:20
	(b) (4)	

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User entered empty.	System	30 Oct 2020 13:16:20

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User entered empty.	System	30 Oct 2020 13:16:20

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:46
User entered empty.	System	30 Oct 2020 13:16:20

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Nov 2020 14:44:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:44:33
Data point term sent to Coder User entered 'ibuprofen'	System Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 14:43:50 09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 17:23:16
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 17:22:33
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 18:43:35
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:12:07
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, the recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:37:19
User entered 'symptomatic covid-19'	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 14:43:44



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:32**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '800'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'as needed (PRN)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '23 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44



US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '25 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	04 Dec 2020 15:12:02
User entered 'Yes (Y)'	(b) (4)	
	Sherry McCammon (b) (4)	09 Nov 2020 14:43:44
	(b) (4)	

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User entered empty.	System	09 Nov 2020 14:43:44

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User entered empty.	System	09 Nov 2020 14:43:44

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:49
User entered empty.	System	09 Nov 2020 14:43:44

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Dec 2020 15:18:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:18:03
Data point term sent to Coder Coding entries removed.	System Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:17:05 04 Dec 2020 15:16:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:48:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 14:48:41
Data point term sent to Coder User entered 'aspirin'	System Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 14:47:58 09 Nov 2020 14:47:57



US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	04 Dec 2020 15:16:26
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	09 Nov 2020 14:47:57
	(b) (4)	

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:47:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:16:31
User entered 'THROMBOSIS prevention' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 15:16:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 14:38:32
User entered 'thrombosis'	Sherry McCammon (b) (4) (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '81'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'mg (mg)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:32**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'once daily (QD)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'Oral (ORAL)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty.	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '29 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '0'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '01 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	09 Nov 2020 14:47:57

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User entered '1'	System	09 Nov 2020 14:47:57

US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User entered '1'	System	09 Nov 2020 14:47:57



US3742477

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:38:50
User entered '804 (804)'	System	09 Nov 2020 14:47:57

US3742477

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:23:32**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:55:43
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	12 Mar 2021 19:24:12
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:23:32

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered '23 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 18:36:01

US3742477

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:23:32

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User closed query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 23:30:19
Query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:44:26
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Per Query Resolution	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 20:44:21
User opened query 'Per CDM; Please consider selecting 'Due to SARS-CoV-2' and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:48:30
User closed query 'Per CDM: AE #6 SYMPTOMATIC COVID-19 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 21:40:45
Query 'Per CDM: AE #6 SYMPTOMATIC COVID-19 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile.' answered with 'Reconciled per query' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 15:37:51
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Nov 2020 15:37:29
User opened query 'Per CDM: AE #6 SYMPTOMATIC COVID-19 records Action taken with investigational product as Investigational Product Withdrawn However, AE is not slecect as primary reason. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:56:57
User entered 'Due to SARS-COV-2 (COVID)'	Sherry McCammon (b) (4) (b) (4)	23 Oct 2020 18:36:01

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:23:32

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 04:11:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
User entered empty; reason for change Per Query Resolution	Kaitlin Mason (b) (4)	18 Nov 2020 20:44:21
User entered 'Symptomatic COVID 19' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Nov 2020 15:37:29
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	05 Nov 2020 14:46:51
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:46:51
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	05 Nov 2020 14:46:39
User entered 'Due to SAE positive COVID19' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Nov 2020 14:46:39
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 18:36:01

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered		
'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09



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Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50
	(b) (4)	

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Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

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Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered		
'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

**US3742477**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:23:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50
	(b) (4)	

**US3742477**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:23:32**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:23:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered '26/Oct/2020 17:00'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:23:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered		
'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09



**US3742477**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:23:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50
	(b) (4)	

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:23:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered '06/Nov/2020 20:17'	System	07 Nov 2020 01:17:33



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:23:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'I'		07 Nov 2020 01:17:33

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered		
'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50
	(b) (4)	

**US3742477**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:23:32**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:23:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered '06/Nov/2020 20:27'	System	07 Nov 2020 01:27:37

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:23:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:14
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'I'		07 Nov 2020 01:27:37

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered		
'USA-US127-2020-MRNA-1273-P301000006'	System	26 Oct 2020 21:00:09

**US3742477**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:23:32**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'No (N)'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Karen'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Kotloff'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '685 W. Baltimore Street, HSF 480'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered 'Baltimore'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 16:24:14
Un-reviewed for Safety.	System	10 Nov 2020 14:16:56
User entered empty.	System	10 Nov 2020 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 14:16:46
User entered 'Maryland'	Kaitlin Mason (b) (4)	09 Nov 2020 17:32:50
	(b) (4)	



US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 18:17:41
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 21:00:43
User entered '21201'	System	26 Oct 2020 21:00:09

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 01:17:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 18:17:41
User entered 'US'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 12 Aug 2021 13:23:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
	(b) (4)	
User entered '4'	System	10 Nov 2020 14:16:56
User entered '3'	System	07 Nov 2020 01:27:37
User entered '2'	System	07 Nov 2020 01:17:33
User entered '1'	System	26 Oct 2020 21:00:50

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:23:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered '10/Nov/2020 09:16'	System	10 Nov 2020 14:16:56

US3742477

Folder: SAE USA-US127-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 12 Aug 2021 13:23:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:27:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:24:14
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:16:56