

US3742169 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:28:34

All time stamps listed in this document are displayed in GMT

US3742169

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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Participant ID

US3742169

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

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US3742169

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 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

US3742169

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3742169

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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

US3742169

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3742169

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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Were any significant conditions reported?

Yes ☒

No ☐

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US3742169

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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



US3742169

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742169

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3742169

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3742169

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3742169

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Condition	LEFT OUTER THIGH PAIN
Start date (dd MMM yyyy)	UN JAN 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3742169

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:22
Height ( <i>xxx.x</i> )	65.8 in
Weight ( <i>xxx.x</i> )	189.5 lb
BMI ( <i>xxx.x</i> )	30.83666 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742169

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3742169

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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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**

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

**No Risk Identified** True

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



US3742169

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

<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>	False
<b>Specify</b>	

US3742169

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 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

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145292

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Height	ND - Not Done
Weight	ND - Not Done

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	08:22 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 08:22
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:07
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3742169

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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.*

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 09:33 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 09:33

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



US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	08:33 (24 HR)
Collection date and time (derived)	31 AUG 2020 08:33

US3742169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:29	31 AUG 2020 08:29
Nasopharyngeal Swab 2	No		

US3742169

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

31 AUG 2020 10:18

PC Open Date & Time

31 AUG 2020 09:53

PC Close Date & Time

31 AUG 2020 12:23

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	31 AUG 2020 21:11
PC Open Date & Time	31 AUG 2020 13:18
PC Close Date & Time	01 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 00:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 11:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 23:14

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 09:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

07 SEP 2020 10:42

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**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

31 AUG 2020 10:18

PC Open Date & Time

31 AUG 2020 09:53

PC Close Date & Time

31 AUG 2020 12:23

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**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

31 AUG 2020 21:14

PC Open Date & Time

31 AUG 2020 13:18

PC Close Date & Time

01 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**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 ☐

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

3

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

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 00:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**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 SEP 2020 11:15

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**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 ☐

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

3

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 23:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**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 SEP 2020 09:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**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 SEP 2020 10:43

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**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 ☐

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 10:19
PC Open Date & Time	31 AUG 2020 09:53
PC Close Date & Time	31 AUG 2020 12:23

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**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 ☐

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 21:18
PC Open Date & Time	31 AUG 2020 13:18
PC Close Date & Time	01 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**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 ☒



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 00:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

49 of 2743

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

51 of 2743

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 11:16
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

53 of 2743

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:16
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

55 of 2743



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 09:06
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**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 ☒

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 10:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:28:34

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

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 9

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 09 SEP 2020 10:30

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 10

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

10 SEP 2020 06:14

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 09:28:34

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 09 SEP 2020 10:30

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

---



US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 10 SEP 2020 06:14

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:34

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

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:28:34

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 10:30
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:28:34

<b>TIMEPOINT</b>	DAY 10
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	10 SEP 2020 06:14
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3742169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	12:01 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 12:01
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 mmHg
Diastolic Blood Pressure units	MMHG

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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	

US3742169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 OCT 2020

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

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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 WITHHELD DUE TO SAE

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? \_\_\_\_\_

US3742169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 OCT 2020
Collection time (00:00-23:59)	12:06 (24 HR)
Collection date and time (derived)	5 OCT 2020 12:06



US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Collection date (dd MMM yyyy)			5 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:05	5 OCT 2020 12:05
Nasopharyngeal Swab 2	No		

US3742169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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

US3742169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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) \_\_\_\_\_

US3742169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

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.*

US3742169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 NOV 2020
Collection time (00:00-23:59)	12:22 (24 HR)
Collection date and time (derived)	19 NOV 2020 12:22

US3742169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:25:24

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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)	False
Chills	True
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 NOV 2020 11:09:21
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Date and time of submission	09 NOV 2020 12:37:05
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	18 NOV 2020 19:37:26
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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	22 NOV 2020 23:06:07
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 13:06:06
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 23:17:32
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 DEC 2020 00:02:31

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 05:50:35

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 DEC 2020 08:50:28

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 01:12:01

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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	08 JAN 2021 13:14:08
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

<b>TIMEPOINT</b>	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 <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	17 JAN 2021 16:18:48
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 01:43:46

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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

31 JAN 2021 09:33:39

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 18:11:28

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 FEB 2021 09:50:47

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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

21 FEB 2021 10:41:05

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 09:31:56
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 11:04:04

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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

28 MAR 2021 17:02:54

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 APR 2021 12:08:26
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 23:09:26

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 APR 2021 00:42:30
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☒

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

23 APR 2021 12:13:02

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 00:08:05

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐ 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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2021 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 <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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 <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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 DEC 2021 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐ 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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 502

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59
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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 <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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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="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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	20 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59
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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59



US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 <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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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 <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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	27 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐  
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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐ 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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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 ☐

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

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19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3742169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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"/>

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

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[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

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**US3742169**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:28:34**

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		14 MAR 2021 11:04:45

US3742169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3742169

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3742169

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

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) \_\_\_\_\_

US3742169

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

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.*

US3742169

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 APR 2021
Collection time (00:00-23:59)	09:17 (24 HR)
Collection date and time (derived)	01 APR 2021 09:17

US3742169

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3742169**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

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*

**US3742169**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

Date of Contact	06 NOV 2020
Time of Contact	12:20
Date and Time of Contact (derived)	06 NOV 2020 12:20
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>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	30 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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)

298 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	31 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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)

302 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	01 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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)

306 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	02 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	03 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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)

314 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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)

318 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

322 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

326 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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)

327 of 2743



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 type="radio"/>
	Mild	<input checked="" 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

334 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 2743



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	09 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

338 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 type="radio"/>
	Mild	<input checked="" 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	10 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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"/>



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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 type="checkbox"/>
Day 13	<input checked="" 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

346 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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 ☐

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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 type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" 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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

	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 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 2743

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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"/>

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

Date of Visit	06 NOV 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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	06 NOV 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)	0

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3742169

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	8 NOV 2020
Day 5	Yes	10 NOV 2020
Day 7	Yes	12 NOV 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	



US3742169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	SICKD1

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 NOV 2020
Time of assessment (00:00-23:59)	12:20 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 12:20
Height (xxx.x)	67.0 in
Weight (xxx.x)	197.0 lb
Temperature (xxx.x)	098.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	063 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)	084 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3742169

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 NOV 2020

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

US3742169

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 17:29:14

Generated On: 10 Jun 2021 09:28:34

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

06 NOV 2020

US3742169

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

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

US3742169

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 19:21:09

Generated On: 10 Jun 2021 09:28:34

Date of updated informed consent ( <i>dd MMM yyyy</i> )	09 FEB 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> )	9 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3742169

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

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

US3742169

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

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)	01 APR 2021
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 09:10
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	064 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	077 mmHg
Diastolic Blood Pressure units	MMHG



US3742169

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

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)	01 APR 2021
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 10:01
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	066 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	079 mmHg
Diastolic Blood Pressure units	MMHG

US3742169

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

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 APR 2021

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

US3742169

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

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

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) 01 APR 2021

What was the treatment time? (00:00-23:59) 09:31 (24 HR)

Treatment Date and Time (derived) 01 APR 2021 09:31

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

US3742169

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00-23:59)	12:33 (24 HR)
Collection date and time (derived)	9 FEB 2021 12:33

US3742169

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00 - 23:59)	12:37
Collection Date and Time (derived)	9 FEB 2021 12:37

US3742169

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

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742169

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742169

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

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



US3742169

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 14:48:51

Generated On: 10 Jun 2021 09:28:34

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 OLD29

US3742169

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 21:27:47

Generated On: 10 Jun 2021 09:28:34

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID

Adverse event

CONSTIPATION

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 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

378 of 2743

EAB) (1725)

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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)	

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID	USA-US127-2020-MRNA-1273-P30 1000003
Adverse event	RHEUMATOID ARTHRITIS
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)	31 AUG 2020
Start time (00:00-23:59)	23:00 (24 HR)
AE start date and time (derived)	31 AUG 2020 23:00
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 checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2743

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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AFTER FIRST VACCINATION, HE REPORTED IN THE E-DIARY MUSCLE AND JOINT ACHE/PAIN THROUGH DAY 7. MUSCLE AND JOINT ACHE/PAIN STARTED AGAIN ON SUNDAY THE 13TH OF SEPTEMBER, BUT WAS DOING BETTER BY TIME OF THE DAY 15 PHONE CALL ON THE 16TH OF SEPTEMBER. LATER THAT DAY, THE JOINT ACHE AND PAIN STARTED AGAIN AND CONTINUED. IT WAS IMPROVED WITH TYLENOL WHICH HE STOPPED TAKING ON THE 24TH OF SEPTEMBER. HE ALSO EXPERIENCED SOME TINNITUS, INSOMNIA AND CONSTIPATION POST VACCINATION. ON 9/29 HE WAS SEEN BY A RHEUMATOLOGIST WHO DIAGNOSED HIM WITH RHEUMATOID ARTHRITIS. SIGNIFICANT LABORATORY RESULTS RETURNED ON 02 OCTOBER 2020 AND INCLUDE RHEUMATOID FACTOR 62.5 IU/ML (NORMAL 0-13) AND ANTI-CCP AB >250 UNITS (NORMAL <20).

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

---

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID	
Adverse event	TINNITUS
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)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

383 of 2743



US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID	
Adverse event	VOMITING
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)	19 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 SEP 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	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

385 of 2743

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID	
Adverse event	INSOMNIA
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)	7 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

387 of 2743

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID

Adverse event

CONSTIPATION

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)

22 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)

09 JAN 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

PRODUCTION RELEASE (v12.003

389 of 2743

EAB) (1725)

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

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

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

AEID

Adverse event

VIRAL ILLNESS UNSPECIFIED

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)

31 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)

14 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

391 of 2743

EAB) (1725)



US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Feb 2021 17:29:12

Generated On: 10 Jun 2021 09:28:34

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

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

Yes ☒

No ☐

---

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

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US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication RABEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 100

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  
EAB) (1725)

396 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication ENALAPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

398 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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"/>



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication BREO ELLIPTA

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 100/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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  
EAB) (1725)

402 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication LEVOCETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

404 of 2743

EAB) (1725)

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

406 of 2743

EAB) (1725)

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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"/>



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication FIBER GUMMIES

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 2

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

If dose unit is Other, specify GUMMIES

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

408 of 2743

EAB) (1725)

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

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

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication PHENYLEPHRINE/ COCOA  
BUTTER 0.25/88%  
SUPPOSITORIES

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 APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

410 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	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 checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication TYLENOL GEL CAPS

Prophylaxis Yes ☐  
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 650

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  
EAB) (1725)

412 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication TRUNATURE DIGESTIBE  
PROBIOTIC

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 2

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

If dose unit is Other, specify GUMMIES

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

414 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input 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"/>



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

416 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	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)		9 OCT 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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication VIRAL ILLNESS UNSPECIFIED

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

418 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication XYZAL

Prophylaxis Yes ☐  
No ☒

Indication VIRAL ILLNESS UNSPECIFIED

Dose per administration 3.75

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  
EAB) (1725)

420 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 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)		14 NOV 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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication MOBIC

Prophylaxis Yes ☐  
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

422 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 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"/>



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication CELEBREX

Prophylaxis Yes ☐  
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

424 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	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)		7 DEC 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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication TRIAMCINOLONE ACETONIDE

Prophylaxis Yes ☐  
No ☒

Indication ELBOW PAIN R/T RHEUMATOID  
ARTHRITIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

426 of 2743

EAB) (1725)

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAARTICULAR	
Start date (dd MMM yyyy)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 DEC 2020	
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"/>

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

Name of Medication HYDROXYCHLOROQUINE

Prophylaxis Yes ☐  
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

428 of 2743

EAB) (1725)

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 07 Apr 2021 21:24:45

Generated On: 10 Jun 2021 09:28:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 MAR 2021	
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"/>

US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 17:29:13

Generated On: 10 Jun 2021 09:28:34

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:48:50

Generated On: 10 Jun 2021 09:28:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
20 NOV 2020	MRI OF LEFT HIP	Other	VIRAL ILLNESS UNSPECIFIED
20 NOV 2020	X-RAY OF NECK	Other	VIRAL ILLNESS UNSPECIFIED



US3742169

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

---

Date of dosing discontinuation (dd MMM yyyy) 3 OCT 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" 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 type="checkbox"/>
Other	<input type="checkbox"/>

---

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

---

US3742169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:34

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 ☐

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/OCT/2020 13:32
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.	True

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:41
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

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/OCT/2020 20:38
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

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/NOV/2020 14:11
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

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/NOV/2020 08:31
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



US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Feb 2021 17:29:14

Generated On: 10 Jun 2021 09:28:34

SAEID	USA-US127-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	MD
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	01/DEC/2020 18:00
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

Audit

US3742169 (Prod: University of Maryland School of Medicine)

**US3742169**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:28:34**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:16
User entered 'US3742169'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 11:54:28

**US3742169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:15:13
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:31

**US3742169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:15:13
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 11:54:29

**US3742169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:15:13
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:31

**US3742169**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'SCRN'	System	31 Aug 2020 13:35:31

US3742169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:34

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:14
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 11:54:30



**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:16
User entered '57'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'YEARS'	System	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '57'	System	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:18
User entered 'Male (M)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

US3742169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:20
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:22
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:24
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:20
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Oct 2020 17:50:31
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58



US3742169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:20
User closed query 'Source states race as Asian. Please verify if correct slot is ticked.' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:05:42
Query 'Source states race as Asian. Please verify if correct slot is ticked.' answered with 'CORRECTED' (Site from CRA).	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:50:41
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:50:31
User opened query 'Source states race as Asian. Please verify if correct slot is ticked.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 20:16:07
User entered '1'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:27
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:28
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:30
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:31
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:34**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:16:33
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:35:58

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Aug 2020'	System	31 Aug 2020 13:36:44



**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '2020'	System	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered 'Amendment 3 (3)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:44

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:12
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 11:54:29

**US3742169**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:34**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'I'	System	31 Aug 2020 13:36:49



**US3742169**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:17
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:36:49

**US3742169**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:28:34**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:22
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:27:13

US3742169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:33:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:33:38
Data point term sent to Coder	System	31 Aug 2020 17:32:55
User entered 'gastroesophageal reflux disease'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'UN UNK 2010' reason for change:	Kaitlin Mason (b) (4)	11 Sep 2020 22:56:35
Data Entry Error	(b) (4)	
User entered '30 Jun 2010'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:32:22



**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Jan 2010'	System	11 Sep 2020 22:56:35
User entered 'Jun 2010'	System	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '2010'	System	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:32:22

**US3742169**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:32:22

US3742169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:34:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:34:40
Data point term sent to Coder	System	31 Aug 2020 17:33:57
User entered 'hypothyroidism'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'UN UNK 1990' reason for change:	Kaitlin Mason (b) (4)	11 Sep 2020 22:56:48
Data Entry Error	(b) (4)	
User entered '30 Jun 1990'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:33:16



**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Jan 1990'	System	11 Sep 2020 22:56:48
User entered 'Jun 1990'	System	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '1990'	System	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:33:16

**US3742169**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:33:16

US3742169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:35:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:35:43
Data point term sent to Coder	System	31 Aug 2020 17:34:57
User entered 'hypertension'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'UN UNK 2018' reason for change:	Kaitlin Mason (b) (4)	11 Sep 2020 22:56:58
Data Entry Error	(b) (4)	
User entered '30 Jun 2018'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:08



**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Jan 2018'	System	11 Sep 2020 22:56:58
User entered 'Jun 2018'	System	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '2018'	System	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:34:08

**US3742169**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:34:08



US3742169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:35:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:35:44
Data point term sent to Coder	System	31 Aug 2020 17:34:58
User entered 'asthma'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'UN UNK 2000' reason for change:	Kaitlin Mason (b) (4)	11 Sep 2020 22:57:16
Data Entry Error	(b) (4)	
User entered '30 Jun 2000'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Jan 2000'	System	11 Sep 2020 22:57:16
User entered 'Jun 2000'	System	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '2000'	System	31 Aug 2020 17:34:39



**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:34:39

**US3742169**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:34:39

US3742169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:36:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:36:32
Data point term sent to Coder	System	31 Aug 2020 17:36:02
User entered 'environmental allergies'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'UN UNK 1990' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:57:26
User entered '30 Jun 1990'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:19:41
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:35:15



**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Jan 1990'	System	11 Sep 2020 22:57:26
User entered 'Jun 1990'	System	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '1990'	System	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:35:15

**US3742169**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	31 Aug 2020 17:35:15

US3742169

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:19:15
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 thigh - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:04:46
Data point term sent to Coder	System	20 Nov 2020 18:00:31
User entered 'Left outer thigh pain'	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:19:15
User entered 'UN Jan 2020'	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:19:15
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:19:15
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:59:46



**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:19:15
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:19:15
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'Jan 2020'	System	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '2020'	System	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered empty.	System	20 Nov 2020 17:59:46

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44



**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered '08:22'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '31 Aug 2020 08:22'	System	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered '65.8' in	Hassan Haji (b) (4)	31 Aug 2020 17:42:44
DataPoint set to visible.	(b) (4) System	31 Aug 2020 13:36:49

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered '189.5' lb	Hassan Haji (b) (4)	31 Aug 2020 17:42:44
DataPoint set to visible.	(b) (4) System	31 Aug 2020 13:36:49

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered '30.83666'	System	31 Aug 2020 17:42:44
DataPoint set to visible.	System	31 Aug 2020 13:36:49

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'kg/m2'	System	31 Aug 2020 17:42:44
DataPoint set to visible.	System	31 Aug 2020 13:36:49

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:48:57
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'DATA HAS BEEN REMOVED' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:36:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:33
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 16:32:31
User entered '097.9' F	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:33
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44



**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:33
User entered '061'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'bpm'	System	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:33
User entered '16'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'breaths/min'	System	31 Aug 2020 17:42:44

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:33
User entered '120'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'mmHg'	System	31 Aug 2020 17:42:44

US3742169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:33
User entered '080'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:44



**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User entered 'mmHg'	System	31 Aug 2020 17:42:44

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49

**US3742169**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49

**US3742169**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:42
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:51

**US3742169**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:42
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:42:51

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31



US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

[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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

[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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31



**US3742169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:28:34**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
User entered 'I'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

**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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

[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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

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)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered '0'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31



**US3742169**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:28:34**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

US3742169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:47:49
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:21:49
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:37:31

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:13
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:14

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:13
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:14

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:13
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:14

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'VISIT1'	System	31 Aug 2020 17:43:14

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 12:59:31

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered '145292'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 12:59:31



**US3742169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 12:59:31

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:34

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:45

US3742169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:34

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:45

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:45

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:28:34**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:45

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:28:34**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:43:45

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:22:18
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 13:37:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:39:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:39:38

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User closed query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:27:27
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:27:25
Query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' answered with 'ND HAS BEEN ADDED' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:37:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:54
User opened query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:44:01
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 17:35:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:34:57
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:42:27
User entered '65.8' in	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55



US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User closed query 'Per CDM: Please update Weight with ND.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:03:06
Query 'Per CDM: Please update Weight with ND.' answered with 'DATA REMOVED AND ND ENTERED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 15:46:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:46:07
User opened query 'Per CDM: Please update Weight with ND.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:54:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:34:57
User entered '189.5' lb	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User closed query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:27:27
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:27:25
Query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' answered with 'ND HAS BEEN ADDED' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:37:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:54
User opened query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:44:01
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 17:35:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:34:57
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:42:27
User entered '65.8' in	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User closed query 'Per CDM: Please update Weight with ND.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:03:06
Query 'Per CDM: Please update Weight with ND.' answered with 'DATA REMOVED AND ND ENTERED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 15:46:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:46:07
User opened query 'Per CDM: Please update Weight with ND.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:54:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:34:57
User entered '189.5' lb	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '08:22'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '31 Aug 2020 08:22'	System	31 Aug 2020 17:45:55



US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '097.9' F	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '061'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'bpm'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '16'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'breaths/min'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '120'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55



**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'mmHg'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '080'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'mmHg'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User closed query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:27:27
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:27:25
Query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' answered with 'ND HAS BEEN ADDED' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:37:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 13:36:54
User opened query 'Per CDM: As per CCGs, p 15-16, "ND" must be entered in HT and WT. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:44:01
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 17:35:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:34:57
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:42:27
User entered '65.8' in	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User closed query 'Per CDM: Please update Weight with ND.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 18:03:06
Query 'Per CDM: Please update Weight with ND.' answered with 'DATA REMOVED AND ND ENTERED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 15:46:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 15:46:07
User opened query 'Per CDM: Please update Weight with ND.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:54:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 17:34:57
User entered '189.5' lb	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55



**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '10:07'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '31 Aug 2020 10:07'	System	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '97.8' F	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered 'Other (Other)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered 'forehead'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '066'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'bpm'	System	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '20'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55



**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'breaths/min'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '122'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'mmHg'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:10
User entered '80'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:45:55

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'mmHg'	System	31 Aug 2020 17:45:55

US3742169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:34

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:18
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:42:31
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'ENTERED IN ERROR UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:17:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:17:01
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 16:32:20
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:46:11

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 17:17:01
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:46:11

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 14:08:19



**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 14:08:19

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 14:08:19

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 14:08:19

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered '09:33'	(b) (4), (b) (6)	31 Aug 2020 14:08:19

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '31 Aug 2020 09:33'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	31 Aug 2020 14:08:19

US3742169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:23:35
User entered 'ONCE'	System	31 Aug 2020 14:08:19



**US3742169**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 14:08:19

US3742169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:44
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:12

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:44
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:12

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:23:44
User entered '08:33'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:12

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '31 Aug 2020 08:33'	System	31 Aug 2020 13:38:12

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:24:01
User entered '31 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:28:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:24:01
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32



**US3742169**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:24:01
User entered '08:29'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '31 Aug 2020 08:29'	System	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:24:01
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:24:01
User entered empty.	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	31 Aug 2020 13:38:32

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:24:13
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 17:46:25

**US3742169**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	31 Aug 2020 17:46:25



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:17:53', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c'	System	31 Aug 2020 14:18:12
User entered 'Yes (Y)'	System	31 Aug 2020 14:18:12

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c'	System	31 Aug 2020 14:18:12
User entered '97.8'	System	31 Aug 2020 14:18:12

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c'	System	31 Aug 2020 14:18:12
User entered 'No (N)'	System	31 Aug 2020 14:18:12

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3ce0460-9012-4407-9a5e-a695ec2f839c'	System	31 Aug 2020 14:18:12
User entered '31 Aug 2020 10:18'	System	31 Aug 2020 14:18:12

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 09:53'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 12:23'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 14:08:19



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304'	System	01 Sep 2020 01:11:57
User entered 'Yes (Y)'	System	01 Sep 2020 01:11:57

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:33', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304'	System	01 Sep 2020 01:11:57
User entered '98.0'	System	01 Sep 2020 01:11:57

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304'	System	01 Sep 2020 01:11:57
User entered 'No (N)'	System	01 Sep 2020 01:11:57

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:11:54', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '773cb424-22a0-4c1b-8b7f-83699124b304'	System	01 Sep 2020 01:11:57
User entered '31 Aug 2020 21:11'	System	01 Sep 2020 01:11:57

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 13:18'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 2'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-01T23:59:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221'	System	02 Sep 2020 04:00:23
User entered 'Yes (Y)'	System	02 Sep 2020 04:00:23



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221' User entered '97.3'	System	02 Sep 2020 04:00:23
	System	02 Sep 2020 04:00:23

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221'	System	02 Sep 2020 04:00:23
User entered 'No (N)'	System	02 Sep 2020 04:00:23

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b3851b0c-99ee-4870-878f-a79ef3339221'	System	02 Sep 2020 04:00:23
User entered '02 Sep 2020 00:00'	System	02 Sep 2020 04:00:23

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 3'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 4'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:14:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139'	System	04 Sep 2020 15:15:06
User entered 'Yes (Y)'	System	04 Sep 2020 15:15:06



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:14:50', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139' User entered '98.3'	System	04 Sep 2020 15:15:06
	System	04 Sep 2020 15:15:06

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:14:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139'	System	04 Sep 2020 15:15:06
User entered 'No (N)'	System	04 Sep 2020 15:15:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5459e3c8-c75e-45ff-addc-f04514abe139'	System	04 Sep 2020 15:15:06
User entered '04 Sep 2020 11:15'	System	04 Sep 2020 15:15:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 5'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:13:48', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45'	System	05 Sep 2020 03:14:11
User entered 'Yes (Y)'	System	05 Sep 2020 03:14:11

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:13:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45'	System	05 Sep 2020 03:14:11
User entered '97.5'	System	05 Sep 2020 03:14:11



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45'	System	05 Sep 2020 03:14:11
User entered 'No (N)'	System	05 Sep 2020 03:14:11

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'f7a5c7ef-ee77-47c4-924a-fda3bbd45b45'	System	05 Sep 2020 03:14:11
User entered '04 Sep 2020 23:14'	System	05 Sep 2020 03:14:11

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 6'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd'	System	06 Sep 2020 13:05:15
User entered 'Yes (Y)'	System	06 Sep 2020 13:05:15

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd'	System	06 Sep 2020 13:05:15
User entered '97.6'	System	06 Sep 2020 13:05:15

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd'	System	06 Sep 2020 13:05:15
User entered 'No (N)'	System	06 Sep 2020 13:05:15



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4a1676f4-26da-4e4f-b0c7-88a7f1bcc8cd'	System	06 Sep 2020 13:05:15
User entered '06 Sep 2020 09:05'	System	06 Sep 2020 13:05:15

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 7'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946'	System	07 Sep 2020 14:42:50
User entered 'Yes (Y)'	System	07 Sep 2020 14:42:50

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946'	System	07 Sep 2020 14:42:50
User entered '98.1'	System	07 Sep 2020 14:42:50

US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946'	System	07 Sep 2020 14:42:50
User entered 'No (N)'	System	07 Sep 2020 14:42:50

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '151cffc4-8b71-4eeb-8300-c7c38b7ff946'	System	07 Sep 2020 14:42:50
User entered '07 Sep 2020 10:42'	System	07 Sep 2020 14:42:50



US3742169

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0'	System	31 Aug 2020 14:18:45
User entered 'None (1)'	System	31 Aug 2020 14:18:45

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0'	System	31 Aug 2020 14:18:45
User entered 'No (N)'	System	31 Aug 2020 14:18:45

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:33', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0'	System	31 Aug 2020 14:18:45
User entered 'No (N)'	System	31 Aug 2020 14:18:45

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0'	System	31 Aug 2020 14:18:45
User entered 'None (1)'	System	31 Aug 2020 14:18:45

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ec48bce6-1a07-4814-834a-d5683b4577c0'	System	31 Aug 2020 14:18:45
User entered '31 Aug 2020 10:18'	System	31 Aug 2020 14:18:45



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 09:53'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 12:23'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:12:49', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799'	System	01 Sep 2020 01:14:43
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 01:14:43

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:12:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799'	System	01 Sep 2020 01:14:43
User entered 'No (N)'	System	01 Sep 2020 01:14:43

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:13:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799'	System	01 Sep 2020 01:14:43
User entered 'No (N)'	System	01 Sep 2020 01:14:43

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:14:31', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799'	System	01 Sep 2020 01:14:43
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 01:14:43

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:14:40', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37c9a9b-4dfa-43e7-9d38-69cbf53e4799'	System	01 Sep 2020 01:14:43
User entered '31 Aug 2020 21:14'	System	01 Sep 2020 01:14:43



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 13:18'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 2'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:23', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d'	System	02 Sep 2020 04:00:52
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 04:00:52

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d'	System	02 Sep 2020 04:00:52
User entered 'Yes (Y)'	System	02 Sep 2020 04:00:52

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:36', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d' User entered '3'	System	02 Sep 2020 04:00:52
	System	02 Sep 2020 04:00:52

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:40', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d'	System	02 Sep 2020 04:00:52
User entered 'No (N)'	System	02 Sep 2020 04:00:52

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d'	System	02 Sep 2020 04:00:52
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 04:00:52



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:00:47', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'decee5b6-4938-466c-af8c-a39da513356d'	System	02 Sep 2020 04:00:52
User entered '02 Sep 2020 00:00'	System	02 Sep 2020 04:00:52

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 3'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 4'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee'	System	04 Sep 2020 15:15:54
User entered 'None (1)'	System	04 Sep 2020 15:15:54

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee'	System	04 Sep 2020 15:15:54
User entered 'No (N)'	System	04 Sep 2020 15:15:54



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee'	System	04 Sep 2020 15:15:54
User entered 'No (N)'	System	04 Sep 2020 15:15:54

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee'	System	04 Sep 2020 15:15:54
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 15:15:54

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:15:52', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '385d22c9-f3ed-4cd1-a400-4684742dcfee'	System	04 Sep 2020 15:15:54
User entered '04 Sep 2020 11:15'	System	04 Sep 2020 15:15:54

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 5'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:16', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231'	System	05 Sep 2020 03:15:08
User entered 'None (1)'	System	05 Sep 2020 03:15:08

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:27', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231'	System	05 Sep 2020 03:15:08
User entered 'Yes (Y)'	System	05 Sep 2020 03:15:08



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231' User entered '3'	System	05 Sep 2020 03:15:08
	System	05 Sep 2020 03:15:08

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231'	System	05 Sep 2020 03:15:08
User entered 'No (N)'	System	05 Sep 2020 03:15:08

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:14:59', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231'	System	05 Sep 2020 03:15:08
User entered 'None (1)'	System	05 Sep 2020 03:15:08

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bfc9fd29-9af5-49e2-9b33-754acbc53231'	System	05 Sep 2020 03:15:08
User entered '04 Sep 2020 23:15'	System	05 Sep 2020 03:15:08

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 6'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0'	System	06 Sep 2020 13:05:35
User entered 'None (1)'	System	06 Sep 2020 13:05:35



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:23', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0'	System	06 Sep 2020 13:05:35
User entered 'No (N)'	System	06 Sep 2020 13:05:35

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:26', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0'	System	06 Sep 2020 13:05:35
User entered 'No (N)'	System	06 Sep 2020 13:05:35

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0'	System	06 Sep 2020 13:05:35
User entered 'None (1)'	System	06 Sep 2020 13:05:35

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd37ca948-fc97-44d6-8fb1-f58a27853bd0'	System	06 Sep 2020 13:05:35
User entered '06 Sep 2020 09:05'	System	06 Sep 2020 13:05:35

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 7'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:42:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c'	System	07 Sep 2020 14:43:33
User entered 'None (1)'	System	07 Sep 2020 14:43:33



US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c'	System	07 Sep 2020 14:43:33
User entered 'No (N)'	System	07 Sep 2020 14:43:33

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c'	System	07 Sep 2020 14:43:33
User entered 'No (N)'	System	07 Sep 2020 14:43:33

US3742169

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:27', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c'	System	07 Sep 2020 14:43:33
User entered 'None (1)'	System	07 Sep 2020 14:43:33

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'ba50c59d-d3e5-429c-bb0e-43d5e753d38c'	System	07 Sep 2020 14:43:33
User entered '07 Sep 2020 10:43'	System	07 Sep 2020 14:43:33

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:47', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'None (0)'	System	31 Aug 2020 14:19:10



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:51', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'None (0)'	System	31 Aug 2020 14:19:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'None (0)'	System	31 Aug 2020 14:19:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:18:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'None (0)'	System	31 Aug 2020 14:19:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'None (0)'	System	31 Aug 2020 14:19:10

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'None (0)'	System	31 Aug 2020 14:19:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered 'No (N)'	System	31 Aug 2020 14:19:10

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T10:19:09', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '38928d7e-43a0-4f3b-ae8f-4e46f3d19f07'	System	31 Aug 2020 14:19:10
User entered '31 Aug 2020 10:19'	System	31 Aug 2020 14:19:10

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 09:53'	System	31 Aug 2020 14:08:19



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 12:23'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:16:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'No interference with activity (1)'	System	01 Sep 2020 01:18:08

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:16:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'No interference with activity (1)'	System	01 Sep 2020 01:18:08

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:16:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'Some interference with activity (2)'	System	01 Sep 2020 01:18:08

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:17:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'Some interference with activity (2)'	System	01 Sep 2020 01:18:08

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:17:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Sep 2020 01:18:08

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:17:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'Some interference with activity not requiring medical attention (2)'	System	01 Sep 2020 01:18:08



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:18:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered 'No (N)'	System	01 Sep 2020 01:18:08

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-08-31T21:18:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e5d4861f-1796-424f-9bc3-f8553c1785c5'	System	01 Sep 2020 01:18:08
User entered '31 Aug 2020 21:18'	System	01 Sep 2020 01:18:08

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '31 Aug 2020 13:18'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 2'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'No interference with activity (1)'	System	02 Sep 2020 04:01:54

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:12', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'Some interference with activity (2)'	System	02 Sep 2020 04:01:54

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:17', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'Some interference with activity (2)'	System	02 Sep 2020 04:01:54



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:20', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'No interference with activity (1)'	System	02 Sep 2020 04:01:54

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:30', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 04:01:54

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'Some interference with activity not requiring medical attention (2)'	System	02 Sep 2020 04:01:54

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered 'No (N)'	System	02 Sep 2020 04:01:54

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-02T00:01:49', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fe009847-4e0e-41fa-ae21-f338f81a2af3'	System	02 Sep 2020 04:01:54
User entered '02 Sep 2020 00:01'	System	02 Sep 2020 04:01:54

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 3'	System	31 Aug 2020 14:08:19



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 4'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 15:16:55

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 15:16:55

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 15:16:55

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 15:16:55

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 15:16:55



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'None (0)'	System	04 Sep 2020 15:16:55

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered 'No (N)'	System	04 Sep 2020 15:16:55

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T11:16:52', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5ae300ad-e476-4a12-bc4f-001d770b5207'	System	04 Sep 2020 15:16:55
User entered '04 Sep 2020 11:16'	System	04 Sep 2020 15:16:55

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 5'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'No interference with activity (1)'	System	05 Sep 2020 03:16:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'No interference with activity (1)'	System	05 Sep 2020 03:16:10



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:22', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'No interference with activity (1)'	System	05 Sep 2020 03:16:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'Some interference with activity (2)'	System	05 Sep 2020 03:16:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	05 Sep 2020 03:16:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:15:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'No interference with activity (1)'	System	05 Sep 2020 03:16:10

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:16:03', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered 'No (N)'	System	05 Sep 2020 03:16:10

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-04T23:16:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cfcc26e0-c85a-43f6-b84a-102835e46fd9'	System	05 Sep 2020 03:16:10
User entered '04 Sep 2020 23:16'	System	05 Sep 2020 03:16:10

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 14:08:19



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 6'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'None (0)'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:51', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'No interference with activity (1)'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'None (0)'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:05:59', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'None (0)'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:06:02', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered 'No (N)'	System	06 Sep 2020 13:06:19



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-06T09:06:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd193f6f8-27ae-42c8-8d86-94a47684e909'	System	06 Sep 2020 13:06:19
User entered '06 Sep 2020 09:06'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 7'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcd0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'None (0)'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcd0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'None (0)'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:54', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'No interference with activity (1)'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:43:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'No interference with activity (1)'	System	07 Sep 2020 14:44:19



US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcd0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'None (0)'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:08', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcd0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'None (0)'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:11', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcd0a3e-bdc0-4b1f-9072-f2c36bd314ef'	System	07 Sep 2020 14:44:19
User entered 'No (N)'	System	07 Sep 2020 14:44:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-07T10:44:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'bcda0a3e-bdc0-4b1f-9072-f2c36bd314ef' User entered '07 Sep 2020 10:44'	System	07 Sep 2020 14:44:19
	System	07 Sep 2020 14:44:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 14:08:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 14:08:19

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	06 Sep 2020 13:06:19
User entered 'Day 8'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	07 Sep 2020 14:44:19
User entered 'Day 9'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:29:56', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3a2d239-b94c-42d8-90ce-601cbc018b70'	System	09 Sep 2020 14:30:06
User entered 'No interference with activity (1)'	System	09 Sep 2020 14:30:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c3a2d239-b94c-42d8-90ce-601cbc018b70'	System	09 Sep 2020 14:30:06
User entered '09 Sep 2020 10:30'	System	09 Sep 2020 14:30:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:44:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:44:19



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	09 Sep 2020 14:30:06
User entered 'Day 10'	System	09 Sep 2020 14:30:06

US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5e1f8967-69c5-4411-b73d-579f65b65f71'	System	10 Sep 2020 10:14:37
User entered 'None (0)'	System	10 Sep 2020 10:14:37

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:33', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5e1f8967-69c5-4411-b73d-579f65b65f71'	System	10 Sep 2020 10:14:37
User entered '10 Sep 2020 06:14'	System	10 Sep 2020 10:14:37

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 14:30:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 14:30:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	06 Sep 2020 13:06:19
User entered 'Day 8'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 10 Jun 2021 09:28:34

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	07 Sep 2020 14:44:19
User entered 'Day 9'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 10 Jun 2021 09:28:34

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a5da341d-1b29-4498-ae50-162335964cf4'	System	09 Sep 2020 14:30:14
User entered 'No interference with activity (1)'	System	09 Sep 2020 14:30:14

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a5da341d-1b29-4498-ae50-162335964cf4'	System	09 Sep 2020 14:30:14
User entered '09 Sep 2020 10:30'	System	09 Sep 2020 14:30:14

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:44:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:44:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	09 Sep 2020 14:30:14
User entered 'Day 10'	System	09 Sep 2020 14:30:14



US3742169

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(10)

Generated On: 10 Jun 2021 09:28:34

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '23daf9f8-6c3a-4cf9-95e7-522b67e13b79'	System	10 Sep 2020 10:14:44
User entered 'None (0)'	System	10 Sep 2020 10:14:44

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '23daf9f8-6c3a-4cf9-95e7-522b67e13b79'	System	10 Sep 2020 10:14:44
User entered '10 Sep 2020 06:14'	System	10 Sep 2020 10:14:44

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 14:30:14

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 14:30:14

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	06 Sep 2020 13:06:19
User entered 'Day 8'	System	06 Sep 2020 13:06:19

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '07 Sep 2020 12:00'	System	06 Sep 2020 13:06:19



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '08 Sep 2020 11:59'	System	06 Sep 2020 13:06:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	07 Sep 2020 14:44:19
User entered 'Day 9'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0e4f307c-afda-4314-a406-ff5145478392'	System	09 Sep 2020 14:30:32
User entered 'No (N)'	System	09 Sep 2020 14:30:32

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-09T10:30:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0e4f307c-afda-4314-a406-ff5145478392'	System	09 Sep 2020 14:30:32
User entered '09 Sep 2020 10:30'	System	09 Sep 2020 14:30:32

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '08 Sep 2020 12:00'	System	07 Sep 2020 14:44:19

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '09 Sep 2020 11:59'	System	07 Sep 2020 14:44:19

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:28:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	09 Sep 2020 14:30:06
User entered 'Day 10'	System	09 Sep 2020 14:30:06

US3742169

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:28:34

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 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5edc8a11-524e-42ea-abb3-bc398249392f'	System	10 Sep 2020 10:14:50
User entered 'No (N)'	System	10 Sep 2020 10:14:50



**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-09-10T06:14:48', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5edc8a11-524e-42ea-abb3-bc398249392f'	System	10 Sep 2020 10:14:50
User entered '10 Sep 2020 06:14'	System	10 Sep 2020 10:14:50

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 14:30:06

**US3742169**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:28:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 14:30:06

**US3742169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:25:15
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 16:11:13

**US3742169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:18:45
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 00:05:57
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 00:05:57
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:25:15
User entered '9 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 16:11:13

**US3742169**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:25:15
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 16:11:13

US3742169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:25:15
User entered empty.	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 16:11:13

**US3742169**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:25:33
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	09 Sep 2020 16:11:21



**US3742169**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	09 Sep 2020 16:11:21

**US3742169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:56
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 14:56:43

**US3742169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:56
User entered '16 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 14:56:43

**US3742169**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:56
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 14:56:43

US3742169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:35:56
User entered empty.	Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 14:56:43

**US3742169**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:36:01
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	17 Sep 2020 14:56:51

**US3742169**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	17 Sep 2020 14:56:51

**US3742169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:36:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:03:38



**US3742169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:36:08
User entered '23 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 14:03:38

**US3742169**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:36:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 14:03:38

US3742169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:36:08
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:03:38

**US3742169**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 19:36:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 14:03:56

**US3742169**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	06 Oct 2020 14:03:56

US3742169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
User closed query 'per CDM: please complete exposure form' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 12:34:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:54:48
Query 'per CDM: please complete exposure form' answered with 'completed' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 12:37:27
User opened query 'per CDM: please complete exposure form' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:15:41
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:48
User entered '5 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:48
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:35



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'VISIT2'	System	13 Oct 2020 16:53:35

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	13 Oct 2020 16:56:55
	(b) (4)	

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '5 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '12:01'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '5 Oct 2020 12:01'	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '097.9' F	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '066'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'bpm'	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '15'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'breaths/min'	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '117'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'mmHg'	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered '083'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55



US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'mmHg'	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	13 Oct 2020 16:56:55
	(b) (4)	

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:56:55



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	13 Oct 2020 16:56:55

US3742169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:58:15

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:54:57
User entered '5 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:58:15

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 15:42:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 15:42:35

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered 'WITHHELD DUE TO SAE'	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 15:42:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	24 Oct 2020 15:42:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 15:42:35



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 15:42:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	24 Oct 2020 15:42:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	24 Oct 2020 15:42:35

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:55:25
User entered empty.	System	24 Oct 2020 15:42:35

US3742169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	24 Oct 2020 15:42:35

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:31
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:54:21

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:31
User entered '5 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:54:21

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:31
User entered '12:06'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:54:21



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '5 Oct 2020 12:06'	System	13 Oct 2020 16:54:21

US3742169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:47
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 16:54:04
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		13 Oct 2020 16:54:04
User entered '5 Oct 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:54:04
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Oct 2020 16:53:49
User entered '13 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:28:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:47
User entered '12:05'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '5 Oct 2020 12:05'	System	13 Oct 2020 16:54:04
User entered '13 Oct 2020 12:05'	System	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:47
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:49



**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	13 Oct 2020 16:53:49

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:00
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:59:48

**US3742169**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	13 Oct 2020 16:59:48

**US3742169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:42
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:00:41

**US3742169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:42
User entered '12 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:00:41

**US3742169**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:42
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:00:41

US3742169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:42
User entered empty.	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:00:41



**US3742169**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:55:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:00:47

**US3742169**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	13 Oct 2020 17:00:47

**US3742169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:41
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Oct 2020 19:31:45

**US3742169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:41
User entered '19 Oct 2020'	Hassan Haji (b) (4) (b) (4)	19 Oct 2020 19:31:45

**US3742169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:41
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4) (b) (4)	19 Oct 2020 19:31:45

**US3742169**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:41
User entered empty.	Hassan Haji (b) (4) (b) (4)	19 Oct 2020 19:31:45

**US3742169**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:46
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Oct 2020 19:32:23

**US3742169**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	19 Oct 2020 19:32:23



**US3742169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:53
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:32:06

**US3742169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:53
User entered '26 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:32:06

**US3742169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:53
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:32:06

**US3742169**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:53
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:32:06

**US3742169**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:58
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:33:02

**US3742169**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	27 Oct 2020 16:33:02

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:16:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 18:10:15

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:16:47
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 18:10:15



**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:16:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Nov 2020 18:10:15

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'VISIT3'	System	19 Nov 2020 18:10:15

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24



**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:04
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:10:24



**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered empty.	System	19 Nov 2020 18:10:24

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:14
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 18:11:15

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:14
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:11:15

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 18:11:25

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:21
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 18:11:25

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:21
User entered '12:22'	(b) (4), (b) (6)	19 Nov 2020 18:11:25



**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered '19 Nov 2020 12:22'	System	19 Nov 2020 18:11:25

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:17:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 18:15:48

**US3742169**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	19 Nov 2020 18:15:48

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 64'	System	31 Aug 2020 14:08:19

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:07:58', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered 'Yes (Y)'	System	04 Nov 2020 16:09:30

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:08:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered 'No (N)'	System	04 Nov 2020 16:09:30

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:08:10', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered 'Yes (Y)'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' User entered '0'	System	04 Nov 2020 16:09:30
	System	04 Nov 2020 16:09:30



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '1'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '1'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '1'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '1'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' User entered '0'	System	04 Nov 2020 16:09:30
	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '1'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270' User entered '0'	System	04 Nov 2020 16:09:30
	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '0'	System	04 Nov 2020 16:09:30



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:15', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered 'No (N)'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-04T11:09:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'dbc3906a-9d4e-4c37-a65a-c3e935003270'	System	04 Nov 2020 16:09:30
User entered '04 Nov 2020 11:09:21'	System	04 Nov 2020 16:09:30

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 71'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:34', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31'	System	09 Nov 2020 17:37:16
User entered 'Yes (Y)'	System	09 Nov 2020 17:37:16

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:43', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31'	System	09 Nov 2020 17:37:16
User entered 'No (N)'	System	09 Nov 2020 17:37:16



US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:50', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31'	System	09 Nov 2020 17:37:16
User entered 'No (N)'	System	09 Nov 2020 17:37:16

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:36:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31'	System	09 Nov 2020 17:37:16
User entered 'Yes (Y)'	System	09 Nov 2020 17:37:16

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:37:02', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31'	System	09 Nov 2020 17:37:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 17:37:16

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-09T12:37:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '50263d56-511d-4c80-a0a2-b67169483d31'	System	09 Nov 2020 17:37:16
User entered '09 Nov 2020 12:37:05'	System	09 Nov 2020 17:37:16

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered 'Day 78'	System	31 Aug 2020 14:08:19

US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-18T19:37:19', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '6459a4cc-7be2-4c34-b2d7-a377191a4e06'	System	19 Nov 2020 00:37:29
User entered 'No (N)'	System	19 Nov 2020 00:37:29



US3742169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-18T19:37:22', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '6459a4cc-7be2-4c34-b2d7-a377191a4e06'	System	19 Nov 2020 00:37:29
User entered 'No (N)'	System	19 Nov 2020 00:37:29

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-18T19:37:26', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '6459a4cc-7be2-4c34-b2d7-a377191a4e06'	System	19 Nov 2020 00:37:29
User entered '18 Nov 2020 19:37:26'	System	19 Nov 2020 00:37:29

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:00:06
Data entry locked.	System	31 Aug 2020 14:08:19
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 14:08:19

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2020-11-22T23:05:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7d631077-9363-468a-9b04-b12ab8ba2768'	System	23 Nov 2020 04:06:11
User entered 'No (N)'	System	23 Nov 2020 04:06:11

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2020-11-22T23:06:04', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7d631077-9363-468a-9b04-b12ab8ba2768'	System	23 Nov 2020 04:06:11
User entered 'No (N)'	System	23 Nov 2020 04:06:11

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-22T23:06:07', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7d631077-9363-468a-9b04-b12ab8ba2768'	System	23 Nov 2020 04:06:11
User entered '22 Nov 2020 23:06:07'	System	23 Nov 2020 04:06:11



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2020-11-27T13:05:55', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5743d0d5-28a5-49b3-b510-e85f276fdd10'	System	27 Nov 2020 18:06:10
User entered 'No (N)'	System	27 Nov 2020 18:06:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2020-11-27T13:06:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5743d0d5-28a5-49b3-b510-e85f276fdd10'	System	27 Nov 2020 18:06:10
User entered 'No (N)'	System	27 Nov 2020 18:06:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-11-27T13:06:06', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '5743d0d5-28a5-49b3-b510-e85f276fdd10'	System	27 Nov 2020 18:06:10
User entered '27 Nov 2020 13:06:06'	System	27 Nov 2020 18:06:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2020-12-04T23:17:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b67415e5-f7f0-4209-87ff-35b8bc2842f7'	System	05 Dec 2020 04:17:36
User entered 'No (N)'	System	05 Dec 2020 04:17:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2020-12-04T23:17:29', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b67415e5-f7f0-4209-87ff-35b8bc2842f7'	System	05 Dec 2020 04:17:36
User entered 'No (N)'	System	05 Dec 2020 04:17:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-12-04T23:17:32', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b67415e5-f7f0-4209-87ff-35b8bc2842f7'	System	05 Dec 2020 04:17:36
User entered '04 Dec 2020 23:17:32'	System	05 Dec 2020 04:17:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2020-12-09T00:02:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0332ff83-e994-46c3-bd2e-201950a393a1'	System	09 Dec 2020 05:02:35
User entered 'No (N)'	System	09 Dec 2020 05:02:35



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2020-12-09T00:02:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0332ff83-e994-46c3-bd2e-201950a393a1'	System	09 Dec 2020 05:02:35
User entered 'No (N)'	System	09 Dec 2020 05:02:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-12-09T00:02:31', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0332ff83-e994-46c3-bd2e-201950a393a1'	System	09 Dec 2020 05:02:35
User entered '09 Dec 2020 00:02:31'	System	09 Dec 2020 05:02:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2020-12-18T05:50:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0ec77ca8-3ac5-4497-a667-cc91a91985e5'	System	18 Dec 2020 10:50:40
User entered 'No (N)'	System	18 Dec 2020 10:50:40

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2020-12-18T05:50:30', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0ec77ca8-3ac5-4497-a667-cc91a91985e5'	System	18 Dec 2020 10:50:40
User entered 'No (N)'	System	18 Dec 2020 10:50:40

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-12-18T05:50:35', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '0ec77ca8-3ac5-4497-a667-cc91a91985e5'	System	18 Dec 2020 10:50:40
User entered '18 Dec 2020 05:50:35'	System	18 Dec 2020 10:50:40



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2020-12-24T08:50:18', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7440fc01-a6f5-41fb-b3bc-5f80e5f99ebd'	System	24 Dec 2020 13:50:32
User entered 'No (N)'	System	24 Dec 2020 13:50:32

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2020-12-24T08:50:22', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7440fc01-a6f5-41fb-b3bc-5f80e5f99ebd'	System	24 Dec 2020 13:50:32
User entered 'No (N)'	System	24 Dec 2020 13:50:32

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2020-12-24T08:50:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7440fc01-a6f5-41fb-b3bc-5f80e5f99ebd' User entered '24 Dec 2020 08:50:28'	System	24 Dec 2020 13:50:32
	System	24 Dec 2020 13:50:32

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-01-03T01:11:54', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a3fbcad8-91a6-47e2-b035-39218f8d7074'	System	03 Jan 2021 06:12:09
User entered 'No (N)'	System	03 Jan 2021 06:12:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-01-03T01:11:57', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a3fbcad8-91a6-47e2-b035-39218f8d7074'	System	03 Jan 2021 06:12:09
User entered 'No (N)'	System	03 Jan 2021 06:12:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-01-03T01:12:01', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a3fbcad8-91a6-47e2-b035-39218f8d7074'	System	03 Jan 2021 06:12:09
User entered '03 Jan 2021 01:12:01'	System	03 Jan 2021 06:12:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-01-08T13:13:56', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e7059ce9-a18c-4d05-bf98-ca48652ca256'	System	08 Jan 2021 18:14:10
User entered 'No (N)'	System	08 Jan 2021 18:14:10



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-01-08T13:14:02', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e7059ce9-a18c-4d05-bf98-ca48652ca256'	System	08 Jan 2021 18:14:10
User entered 'No (N)'	System	08 Jan 2021 18:14:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-01-08T13:14:08', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e7059ce9-a18c-4d05-bf98-ca48652ca256'	System	08 Jan 2021 18:14:10
User entered '08 Jan 2021 13:14:08'	System	08 Jan 2021 18:14:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-01-17T16:18:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fdad7576-e535-41fd-b681-44ec8e3e75a7'	System	17 Jan 2021 21:18:54
User entered 'No (N)'	System	17 Jan 2021 21:18:54

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-01-17T16:18:45', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fdad7576-e535-41fd-b681-44ec8e3e75a7'	System	17 Jan 2021 21:18:54
User entered 'No (N)'	System	17 Jan 2021 21:18:54

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-01-17T16:18:48', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'fdad7576-e535-41fd-b681-44ec8e3e75a7'	System	17 Jan 2021 21:18:54
User entered '17 Jan 2021 16:18:48'	System	17 Jan 2021 21:18:54



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-01-22T01:43:38', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '1369ee01-7065-4f3c-9ddb-58055774c8b2'	System	22 Jan 2021 06:43:50
User entered 'No (N)'	System	22 Jan 2021 06:43:50

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-01-22T01:43:42', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '1369ee01-7065-4f3c-9ddb-58055774c8b2'	System	22 Jan 2021 06:43:50
User entered 'No (N)'	System	22 Jan 2021 06:43:50

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-01-22T01:43:46', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '1369ee01-7065-4f3c-9ddb-58055774c8b2'	System	22 Jan 2021 06:43:50
User entered '22 Jan 2021 01:43:46'	System	22 Jan 2021 06:43:50

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-01-31T09:33:21', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7df7c550-76d7-42e6-8b59-3a54e7877654'	System	31 Jan 2021 14:33:43
User entered 'No (N)'	System	31 Jan 2021 14:33:43

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-01-31T09:33:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7df7c550-76d7-42e6-8b59-3a54e7877654'	System	31 Jan 2021 14:33:43
User entered 'No (N)'	System	31 Jan 2021 14:33:43

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-01-31T09:33:39', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '7df7c550-76d7-42e6-8b59-3a54e7877654'	System	31 Jan 2021 14:33:43
User entered '31 Jan 2021 09:33:39'	System	31 Jan 2021 14:33:43

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-02-04T18:11:22', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b73a1d41-aaca-4a22-b8cb-341924cf6daf'	System	04 Feb 2021 23:13:02
User entered 'No (N)'	System	04 Feb 2021 23:13:02



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-02-04T18:11:25', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b73a1d41-aaca-4a22-b8cb-341924cf6daf'	System	04 Feb 2021 23:13:02
User entered 'No (N)'	System	04 Feb 2021 23:13:02

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-02-04T18:11:28', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b73a1d41-aaca-4a22-b8cb-341924cf6daf'	System	04 Feb 2021 23:13:02
User entered '04 Feb 2021 18:11:28'	System	04 Feb 2021 23:13:02

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-02-14T09:50:34', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c6186e35-7fa5-4990-98f6-af6bfe60349e'	System	14 Feb 2021 14:50:51
User entered 'No (N)'	System	14 Feb 2021 14:50:51

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-02-14T09:50:41', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c6186e35-7fa5-4990-98f6-af6bfe60349e'	System	14 Feb 2021 14:50:51
User entered 'No (N)'	System	14 Feb 2021 14:50:51

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-02-14T09:50:47', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c6186e35-7fa5-4990-98f6-af6bfe60349e' User entered '14 Feb 2021 09:50:47'	System	14 Feb 2021 14:50:51
	System	14 Feb 2021 14:50:51



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-02-21T10:40:59', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cdebe423-dab2-4b7e-b732-9b0c3940d8dc'	System	21 Feb 2021 15:41:09
User entered 'No (N)'	System	21 Feb 2021 15:41:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-02-21T10:41:02', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cdebe423-dab2-4b7e-b732-9b0c3940d8dc'	System	21 Feb 2021 15:41:09
User entered 'No (N)'	System	21 Feb 2021 15:41:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-02-21T10:41:05', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'cdebe423-dab2-4b7e-b732-9b0c3940d8dc'	System	21 Feb 2021 15:41:09
User entered '21 Feb 2021 10:41:05'	System	21 Feb 2021 15:41:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-02-24T09:31:47', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e37e1f38-204c-4280-b513-51bbeb2399cc'	System	24 Feb 2021 14:31:59
User entered 'No (N)'	System	24 Feb 2021 14:31:59

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-02-24T09:31:50', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e37e1f38-204c-4280-b513-51bbeb2399cc'	System	24 Feb 2021 14:31:59
User entered 'No (N)'	System	24 Feb 2021 14:31:59

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-02-24T09:31:56', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'e37e1f38-204c-4280-b513-51bbeb2399cc'	System	24 Feb 2021 14:31:59
User entered '24 Feb 2021 09:31:56'	System	24 Feb 2021 14:31:59

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-03-14T11:03:58-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4d0b5bf7-6f77-40d7-98aa-d962466ab65f'	System	14 Mar 2021 15:04:10
User entered 'No (N)'	System	14 Mar 2021 15:04:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-03-14T11:04:00-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4d0b5bf7-6f77-40d7-98aa-d962466ab65f'	System	14 Mar 2021 15:04:10
User entered 'No (N)'	System	14 Mar 2021 15:04:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-03-14T11:04:04-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '4d0b5bf7-6f77-40d7-98aa-d962466ab65f' User entered '14 Mar 2021 11:04:04'	System	14 Mar 2021 15:04:10

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-03-28T17:02:42-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd5d75cca-c964-4ff6-ab3c-6efae1d32fc'	System	28 Mar 2021 21:02:58
User entered 'No (N)'	System	28 Mar 2021 21:02:58

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-03-28T17:02:49-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd5d75cca-c964-4ff6-ab3c-6efae1d32fc'	System	28 Mar 2021 21:02:58
User entered 'No (N)'	System	28 Mar 2021 21:02:58

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-03-28T17:02:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'd5d75cca-c964-4ff6-ab3c-6efaeed32fc' User entered '28 Mar 2021 17:02:54'	System	28 Mar 2021 21:02:58
	System	28 Mar 2021 21:02:58

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-04-04T12:07:11-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered 'Yes (Y)'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-04-04T12:07:28-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered 'No (N)'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:34-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered 'Yes (Y)'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '0'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '1'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d' User entered '0'	System	04 Apr 2021 16:09:36
	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '0'	System	04 Apr 2021 16:09:36



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d' User entered '0'	System	04 Apr 2021 16:09:36
	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '1'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d' User entered '1'	System	04 Apr 2021 16:09:36
	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '1'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '1'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '1'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '0'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '0'	System	04 Apr 2021 16:09:36



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d' User entered '0'	System	04 Apr 2021 16:09:36
	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d' User entered '0'	System	04 Apr 2021 16:09:36
	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '1'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d' User entered '0'	System	04 Apr 2021 16:09:36
	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '0'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Please 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 (5d08f9985f925456)', Time: '2021-04-04T12:08:04-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:08:19-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered 'No (N)'	System	04 Apr 2021 16:09:36

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-04T12:08:26-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '49add434-2f96-45ff-acd9-3c080b610e2d'	System	04 Apr 2021 16:09:36
User entered '04 Apr 2021 12:08:26'	System	04 Apr 2021 16:09:36



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-04-10T23:09:13-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b5268a3a-5c8a-44fc-b75e-3f2b1f5647d6'	System	11 Apr 2021 03:09:29
User entered 'No (N)'	System	11 Apr 2021 03:09:29

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-04-10T23:09:21-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b5268a3a-5c8a-44fc-b75e-3f2b1f5647d6'	System	11 Apr 2021 03:09:29
User entered 'No (N)'	System	11 Apr 2021 03:09:29

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-10T23:09:26-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'b5268a3a-5c8a-44fc-b75e-3f2b1f5647d6'	System	11 Apr 2021 03:09:29
User entered '10 Apr 2021 23:09:26'	System	11 Apr 2021 03:09:29

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-04-18T00:41:55-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '65e2dc91-8bfd-4ca8-ae6b-8987ea3f32e6'	System	18 Apr 2021 04:42:35
User entered 'Yes (Y)'	System	18 Apr 2021 04:42:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-04-18T00:42:03-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '65e2dc91-8bfd-4ca8-ae6b-8987ea3f32e6'	System	18 Apr 2021 04:42:35
User entered 'No (N)'	System	18 Apr 2021 04:42:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-18T00:42:11-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '65e2dc91-8bfd-4ca8-ae6b-8987ea3f32e6'	System	18 Apr 2021 04:42:35
User entered 'No (N)'	System	18 Apr 2021 04:42:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-18T00:42:17-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '65e2dc91-8bfd-4ca8-ae6b-8987ea3f32e6'	System	18 Apr 2021 04:42:35
User entered 'No (N)'	System	18 Apr 2021 04:42:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-18T00:42:30-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '65e2dc91-8bfd-4ca8-ae6b-8987ea3f32e6'	System	18 Apr 2021 04:42:35
User entered '18 Apr 2021 00:42:30'	System	18 Apr 2021 04:42:35

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-04-23T12:12:52-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a532ce18-b370-46ca-8d70-272436562249'	System	23 Apr 2021 16:14:07
User entered 'No (N)'	System	23 Apr 2021 16:14:07

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-04-23T12:12:58-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a532ce18-b370-46ca-8d70-272436562249'	System	23 Apr 2021 16:14:07
User entered 'No (N)'	System	23 Apr 2021 16:14:07

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-04-23T12:13:02-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'a532ce18-b370-46ca-8d70-272436562249' User entered '23 Apr 2021 12:13:02'	System	23 Apr 2021 16:14:07
	System	23 Apr 2021 16:14:07

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[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 (5d08f9985f925456)', Time: '2021-05-02T00:07:56-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c962f966-0409-45e6-9f11-c3b344218b0c'	System	02 May 2021 04:08:09
User entered 'No (N)'	System	02 May 2021 04:08:09



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

Have you been exposed to someone with 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 (5d08f9985f925456)', Time: '2021-05-02T00:08:01-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c962f966-0409-45e6-9f11-c3b344218b0c'	System	02 May 2021 04:08:09
User entered 'No (N)'	System	02 May 2021 04:08:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-05-02T00:08:05-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: 'c962f966-0409-45e6-9f11-c3b344218b0c'	System	02 May 2021 04:08:09
User entered '02 May 2021 00:08:05'	System	02 May 2021 04:08:09

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:42:28

**US3742169**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:42:28

**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 20:42:28



**US3742169**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:42:28
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 20:42:28

US3742169

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:28:34

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 20:56:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-03-14T11:04:33-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '2e9dbcc5-4f42-421c-bfc5-efcb7e9d1865'	System	14 Mar 2021 15:04:49
User entered 'No (N)'	System	14 Mar 2021 15:04:49

**US3742169**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:56:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5d08f9985f925456)', Time: '2021-03-14T11:04:45-04:00', User OID: 'PatientReportedOutcome (US3742169)', ODM File OID: '2e9dbcc5-4f42-421c-bfc5-efcb7e9d1865'	System	14 Mar 2021 15:04:49
User entered '14 Mar 2021 11:04:45'	System	14 Mar 2021 15:04:49

**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:18:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 14:13:44

**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:18:01
User entered '30 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 14:13:44

**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:18:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Dec 2020 14:13:44

**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:18:01
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 14:13:44

**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:18:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 14:14:14



**US3742169**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:03:29
User entered 'I'	System	01 Dec 2020 14:14:14

**US3742169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:08:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:16:26

**US3742169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User closed query 'Please verify date should be 04 Jan 2021 per source' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 21:39:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:39:01
Query 'Please verify date should be 04 Jan 2021 per source' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 14:16:31
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 14:16:25
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 14:16:25
User opened query 'Please verify date should be 04 Jan 2021 per source' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 21:08:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '18 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 16:16:26

**US3742169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:08:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:16:26

**US3742169**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:08:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:16:26

**US3742169**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:09:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 16:16:43

**US3742169**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User entered 'I'	System	21 Dec 2020 16:16:43

**US3742169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:06:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Feb 2021 13:43:59



US3742169

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:52:56
User closed query 'Please verify date should be 2 Feb 2021 per source' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:58:34
Query 'Please verify date should be 2 Feb 2021 per source' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 14:17:14
Signature has been broken.	(b) (4), (b) (6)	24 Feb 2021 14:17:07
User entered '2 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 14:17:07
User opened query 'Please verify date should be 2 Feb 2021 per source' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 21:06:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '4 Feb 2021'	Sherry McCammon (b) (4)	04 Feb 2021 13:43:59

**US3742169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:06:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	04 Feb 2021 13:43:59

**US3742169**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:06:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered empty.	Sherry McCammon (b) (4)	04 Feb 2021 13:43:59

**US3742169**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:07:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 13:44:11

**US3742169**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User entered 'I'	System	04 Feb 2021 13:44:11

**US3742169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 18:54:33
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 20:39:05

**US3742169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:54:33
User entered '4 Mar 2021'	Sherry McCammon (b) (4)	04 Mar 2021 20:39:05
	(b) (4)	

**US3742169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:54:33
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	04 Mar 2021 20:39:05
	(b) (4)	



**US3742169**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:54:33
User entered empty.	Sherry McCammon (b) (4)	04 Mar 2021 20:39:05
	(b) (4)	

**US3742169**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 18:54:54
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	04 Mar 2021 20:39:25
	(b) (4)	

**US3742169**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:11:29
User entered 'I'	System	04 Mar 2021 20:39:25

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:02
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:19:58

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:02
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:19:58

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:02
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:19:58

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 20:19:58

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05



**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:20:05



**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:10
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:20:05

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:18

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:18



**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:32

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:32

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:32
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered '09:17'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 20:20:32

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 09:17'	System	01 Apr 2021 20:20:32

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:45
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:36:39

**US3742169**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Apr 2021 13:36:39

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:31
User entered '06 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 17:21:14

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:34

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:31
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:22:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 17:22:00
User entered '12:20' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 17:22:00
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:21:14
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:21:14



**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:28:34**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:08
User entered '06 Nov 2020 12:20'	System	10 Nov 2020 17:22:00
User entered empty.	System	10 Nov 2020 17:21:14

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:28:34**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:31
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	10 Nov 2020 17:21:14

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:28:34**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:36:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:21:14

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:25:05

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 19:48:24
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered '06 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-7. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:39:26
Query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-7. If not collected, please consider recording as Not Done.' answered with 'ND- NOT DONE RECORDED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:46:19
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User opened query 'Per CDM: It appears that O2 and Temperature were not collected for Days 1-7. If not collected, please consider recording as Not Done.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 16:51:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	10 Nov 2020 17:25:05



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:25:05

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
DataPoint Un-verified.	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05



**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 2 (Day 2)'	Sherry McCammon (b) (4)	19 Nov 2020 19:48:39

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '31 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:48:39

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:48:39

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:48:39

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	19 Nov 2020 19:48:39

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:48:39

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 3 (Day 3)'	Sherry McCammon (b) (4)	19 Nov 2020 19:49:09



**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '01 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '1 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:49:09

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:09

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	19 Nov 2020 19:49:09

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:09

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 4 (Day 4)'	Sherry McCammon (b) (4)	19 Nov 2020 19:49:33

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '02 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '2 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:49:33



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:33

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	19 Nov 2020 19:49:33

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:33

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 5 (Day 5)'	Sherry McCammon (b) (4)	19 Nov 2020 19:49:44

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '03 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '3 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:49:44

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:44

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	19 Nov 2020 19:49:44



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:44

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:28:34**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:44
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 6 (Day 6)'	Sherry McCammon (b) (4)	19 Nov 2020 19:49:54

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '04 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '4 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:49:54

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:54

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	19 Nov 2020 19:49:54

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:49:54

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:28:34**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:54
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 7 (Day 7)'	Sherry McCammon (b) (4)	19 Nov 2020 19:50:06



**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '05 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '5 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:50:06

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:50:06

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	25 Jan 2021 17:45:52
User entered empty.	System	19 Nov 2020 19:50:06

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:45:52
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	25 Jan 2021 17:45:52
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered empty.	Sherry McCammon (b) (4)	19 Nov 2020 19:50:06

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 8 (Day 8)'	Sherry McCammon (b) (4)	19 Nov 2020 19:50:23

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '06 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '6 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:50:23



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '97' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:50:23

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.0' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:05:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:23
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 9 (Day 9)'	Sherry McCammon (b) (4)	19 Nov 2020 19:50:37

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '07 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '7 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:50:37

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:50:37



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.2' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '08 Nov 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:53:12
User entered '8 Nov 2020'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:50:58

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '94' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:50:58

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.6' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:58
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 11 (Day 11)'	Sherry McCammon (b) (4)	19 Nov 2020 19:51:41



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '09 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:51:41

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:51:41

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:51:41

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.1' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:41
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 12 (Day 12)'	Sherry McCammon (b) (4)	19 Nov 2020 19:51:51

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '10 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:51:51

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:51:51



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '97' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:51:51

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.4' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:51:51
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 13 (Day 13)' reason for change:	(b) (4)	
Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '11 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:52:01

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:52:01

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:52:01



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:01
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 14 (Day 14)'	Sherry McCammon (b) (4)	19 Nov 2020 19:52:17

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '12 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:52:17

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:52:17

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:28:34**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:52:17

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.5' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 15 (Day 15)'	Sherry McCammon (b) (4)	19 Nov 2020 19:52:37



**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '13 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:52:37

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 19:52:37

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:13:33
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User entered '%'	System	19 Nov 2020 20:13:33
User entered empty.	System	19 Nov 2020 19:52:37

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered '98.3' F reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:15:12
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:01:58
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:03:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:04:09
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:55:43
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:59:18
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 19:57:50
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:06:29
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	



US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:08:11
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:09:01
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:10:25
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:11:26
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:28:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:39:08
User entered 'None (None)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:12:16
User entered empty.	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37
	(b) (4)	

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered '06 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 17:28:25

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[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 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 17:28:25

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:34

[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 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:37:42
User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:48:55
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'updated' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	20 Nov 2020 14:44:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	20 Nov 2020 14:44:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:03:19
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:03:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 17:42:04
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 17:42:00
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 17:28:59
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 17:28:25
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:28:25



**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered '06 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 17:28:25

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Nov 2020 17:28:25

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:28:25

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[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 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 17:28:25

US3742169

Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:28:34

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:28:25

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:42:00
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 17:28:25

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:28:34**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:33
User entered '0'	System	20 Nov 2020 14:44:39

**US3742169**

**Folder: Covid-19 Assessment 06 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:27:44
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 19:10:18
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	04 Dec 2020 16:41:32



**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 3 (Day 3)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered '8 Nov 2020'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 5 (Day 5)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered '10 Nov 2020'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 7 (Day 7)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13



**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered '12 Nov 2020'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 9 (Day 9)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'NA (COVID-19 Negative) (NA)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered empty.	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 14 (Day 14)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'NA (COVID-19 Negative) (NA)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered empty.	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 21 (Day 21)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13



**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'NA (COVID-19 Negative) (NA)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered empty.	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User accepted default value 'Day 28 (Day 28)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered 'NA (COVID-19 Negative) (NA)'	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

**US3742169**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:59:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:38:02
User entered empty.	Hassan Haji (b) (4) (b) (4)	19 Nov 2020 15:18:13

US3742169

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:57:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per GCL Lab Reconciliation: it appears PPD Central lab has Swab sample with date 06NOV2020 under illness visit; however, there is no record in EDC. Please confirm the correct visit and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 12:49:06
Query 'Per GCL Lab Reconciliation: it appears PPD Central lab has Swab sample with date 06NOV2020 under illness visit; however, there is no record in EDC. Please confirm the correct visit and update accordingly.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	13 Nov 2020 18:51:30
User opened query 'Per GCL Lab Reconciliation: it appears PPD Central lab has Swab sample with date 06NOV2020 under illness visit; however, there is no record in EDC. Please confirm the correct visit and update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:37:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:45:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:51:34

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:57:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:45:44
User entered '06 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:51:34

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[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 09:57:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:45:44
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:51:34



**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:57:58
User entered 'SICKD1'	System	06 Nov 2020 18:51:34

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '06 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '12:20'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User entered '06 Nov 2020 12:20'	System	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '67.0' in	Sherry McCammon (b) (4)	06 Nov 2020 18:53:20
DataPoint set to visible.	(b) (4) System	06 Nov 2020 18:51:34

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '197.0' lb	Sherry McCammon (b) (4)	06 Nov 2020 18:53:20
DataPoint set to visible.	(b) (4) System	06 Nov 2020 18:51:34

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '098.0' F	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20



**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered 'Oral (Oral)'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered empty.	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '063' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 18:54:01
User entered '097'	(b) (4) Sherry McCammon (b) (4)	06 Nov 2020 18:53:20
	(b) (4)	

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User entered 'bpm'	System	06 Nov 2020 18:53:20

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Nov 2020 18:54:01
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	06 Nov 2020 18:54:01
User entered '14' reason for change: Data Entry Error	Sherry McCammon (b) (4)	06 Nov 2020 18:54:01
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	06 Nov 2020 18:53:20
User entered '063'	Sherry McCammon (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User entered 'breaths/min'	System	06 Nov 2020 18:53:20

US3742169

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '124'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User entered 'mmHg'	System	06 Nov 2020 18:53:20



**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:48:51
User entered '084'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11
User entered 'mmHg'	System	06 Nov 2020 18:53:20

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:11

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:44:46
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:54:57

**US3742169**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:44:46
User entered '06 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:54:57

US3742169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:28:34

[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 09:58:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:40:17
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:55:19

US3742169

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:28:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 09:58:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 08Nov2020 for Day 3 , 10Nov2020 for Day 5 and 12Nov2020 for Day 7 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 08:12:05
Query 'Per GCL Lab Recon: Saliva: Sample dated 08Nov2020 for Day 3 , 10Nov2020 for Day 5 and 12Nov2020 for Day 7 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	19 Nov 2020 15:57:56
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 08Nov2020 for Day 3 , 10Nov2020 for Day 5 and 12Nov2020 for Day 7 is reported under Illness visit in PPD central lab, however saliva log is not completed in EDC. Please complete, thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:32:20
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:40:17
User entered '06 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	06 Nov 2020 18:55:19



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:09:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:39:39

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:09:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:39:39

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[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 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:09:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:39:39

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 16:39:39

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:34

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:35
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 19:21:09
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
Signature has been broken.	(b) (4)	
	Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
	(b) (4)	
User entered '09 Feb 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6 Jan 2021'	(b) (4), (b) (6)	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[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 22:14:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:00:45

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:00:45



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:41:08

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:57:35
User closed query 'Per Sponsor Review: Per IRT, subject did go on to open-label dosing with mRNA. Please review and complete eCRF for open-label Day 1 dosing if needed.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:08:56
User signature succeeded.	Milagritos Tapia (b) (4)	08 Apr 2021 19:21:09
Query 'Per Sponsor Review: Per IRT, subject did go on to open-label dosing with mRNA. Please review and complete eCRF for open-label Day 1 dosing if needed.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	08 Apr 2021 19:18:07
DataPoint Un-verified.	Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
Signature has been broken.	Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
User opened query 'Per Sponsor Review: Per IRT, subject did go on to open-label dosing with mRNA. Please review and complete eCRF for open-label Day 1 dosing if needed.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:35:44
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'No (N)'	(b) (4), (b) (6)	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered empty.	System	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'I'	System	08 Apr 2021 19:17:49
User entered empty.	System	10 Feb 2021 16:41:08

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered empty.	System	10 Apr 2021 13:47:31
DataPoint set to visible.	System	08 Apr 2021 19:17:49

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered empty.	System	10 Apr 2021 13:47:31
DataPoint set to visible.	System	08 Apr 2021 19:17:49

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User accepted default value 'Pre-Dose (PREDOSE)'	Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '01 Apr 2021'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '09:10'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered '01 Apr 2021 09:10'	System	10 Apr 2021 13:47:31

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '97.8' F	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Oral (Oral)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered empty.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '064'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'bpm'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '016'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'breaths/min'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '129'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'mmHg'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '077'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'mmHg'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered missing code ND - Not Done.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:28:34**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered empty.	System	10 Apr 2021 13:47:31
DataPoint set to visible.	System	08 Apr 2021 19:17:49



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User accepted default value 'Post-Dose (POSTDOSE)'	Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '01 Apr 2021'	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '10:01'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered '01 Apr 2021 10:01'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '97.9' F	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Oral (Oral)'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered empty.	Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '066'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'bpm'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '018'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'breaths/min'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '120'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'mmHg'	System	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '079'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'mmHg'	System	10 Apr 2021 13:47:31



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:42
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:48:27

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:58:42
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '01 Apr 2021'	Kaitlin Mason (b) (4)	10 Apr 2021 13:48:27

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	10 Apr 2021 13:49:36
Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	10 Apr 2021 13:49:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	10 Apr 2021 13:49:36
User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	09 Apr 2021 14:51:11
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	09 Apr 2021 14:51:11
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	09 Apr 2021 14:51:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 14:51:11
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	09 Apr 2021 13:31:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 13:31:01

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
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)	10 Apr 2021 13:49:36
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).	System	09 Apr 2021 14:51:11
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:31:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

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 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:31:01

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'mRNA-1273'	System	10 Apr 2021 13:49:36
User entered empty.	System	09 Apr 2021 14:51:11
User entered 'mRNA-1273'	System	09 Apr 2021 13:31:01
DataPoint set to visible.	System	08 Apr 2021 19:17:49

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User closed query 'Per IRT, Subject had Open Label Day1 Treatment on 01APR2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:08:05
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
Query 'Per IRT, Subject had Open Label Day1 Treatment on 01APR2021. Please review and reconcile. ' answered with 'updated' (Site from DM).	(b) (4)	
User entered '01 Apr 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	10 Apr 2021 13:49:46
User entered '09 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 13:31:01
User opened query 'Per IRT, Subject had Open Label Day1 Treatment on 01APR2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:20:09

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '09:31' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	10 Apr 2021 13:49:36
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:31:01



**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:28:34**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered '01 Apr 2021 09:31'	System	10 Apr 2021 13:49:36
User entered empty.	System	09 Apr 2021 13:31:01

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4)	10 Apr 2021 13:49:36
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:31:01

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:14:08
User entered 'ONCE'	System	10 Apr 2021 13:49:36
User entered empty.	System	09 Apr 2021 14:51:11
User entered 'ONCE'	System	09 Apr 2021 13:31:01

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'INTRAMUSCULAR'	System	10 Apr 2021 13:49:36
User entered empty.	System	09 Apr 2021 14:51:11
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 13:31:01

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:04

US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:04

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '12:33'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:04

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered '9 Feb 2021 12:33'	System	10 Feb 2021 16:40:04



US3742169

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:19

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:34**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:19

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:34**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:10:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '12:37'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:40:19

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:34**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered '9 Feb 2021 12:37'	System	10 Feb 2021 16:40:19

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:09:01
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:42:33

**US3742169**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:14:38
User entered 'I'	System	10 Apr 2021 13:42:33

**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:15:35
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:42:51

**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:15:35
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered '08 Apr 2021'	Kaitlin Mason (b) (4)	10 Apr 2021 13:42:51



**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:15:35
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Contact Made (CONTACT MADE)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:42:51

**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:15:35
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered empty.	Kaitlin Mason (b) (4)	10 Apr 2021 13:42:51

**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:15:42
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:43:33

**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Apr 2021 13:43:33

**US3742169**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:34**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Apr 2021 13:43:33
DataPoint set to visible.	System	10 Apr 2021 13:43:33

**US3742169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:16:12
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered 'No (N)'	Kaitlin Mason (b) (4)	10 Apr 2021 13:43:51

**US3742169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:16:12
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered empty.	Kaitlin Mason (b) (4)	10 Apr 2021 13:43:51

**US3742169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:16:12
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User entered empty.	Kaitlin Mason (b) (4)	10 Apr 2021 13:43:51



**US3742169**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:34**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	10 Apr 2021 13:43:51

US3742169

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:28:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:28
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:47
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 10). 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)	05 Mar 2021 10:18:31
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 10). 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 'This is related to AE #2 which was eventually diagnosed as Rheumatoid Arthritis' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:30:21
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES and MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 10). 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 14:26:26
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:27:31
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:02:46

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 08:51:59
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Oct 2020 15:06:58
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:59:26
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 20:06:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 20:06:44
Data point term sent to Coder	System	17 Sep 2020 20:05:28
User entered 'constipation'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '13 Sep 2020'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User entered empty.	System	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:06:01
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 14:00:46
User entered '25 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	06 Oct 2020 14:00:46
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '16 Sep 2020'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User entered empty.	System	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:05:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 20:05:24
User entered 'None (NONE)' reason for change: Data Entry Error	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:24
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 20:05:07
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
DataPoint Un-verified.	Kaitlin Mason (b) (4)	21 Oct 2020 15:07:09
User entered '0' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	21 Oct 2020 15:07:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '1'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

US3742169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
DataPoint Un-verified.	Kaitlin Mason (b) (4)	21 Oct 2020 15:07:09
User entered '1' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	21 Oct 2020 15:07:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	Hassan Haji (b) (4) (b) (4)	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User entered '0'	System	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06
User entered '0'	System	17 Sep 2020 20:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:06

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:19
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	05 Oct 2020 13:32:04

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Rheumatoid Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:41:24
Query 'Per DM CLR: Please review AE and please update to specify the location of Rheumatoid Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'Specific location not necessary per PPD monitor' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 20:00:36
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Rheumatoid Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:20:38
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:11:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:11:43
Data point term sent to Coder	System	03 Oct 2020 15:11:34
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
Coding entries removed.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'RHEUMATOID ARTHRITIS' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:53:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:53:57
Data point term sent to Coder	System	25 Sep 2020 16:03:25
User entered 'JOINT PAIN'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:10:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:33:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:23
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:46:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 14:46:52
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	28 Sep 2020 14:46:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:46:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 14:46:52
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	28 Sep 2020 14:46:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User closed query 'PV Query: Please consider updating start date to date of onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:40:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
	(b) (4)	
Query 'PV Query: Please consider updating start date to date of onset of symptoms.' answered with 'This the earliest day join pains appeared in diary.' (Site from Safety).	Milagritos Tapia (b) (4)	14 Oct 2020 16:58:58
	(b) (4)	
DataPoint Un-verified.	Milagritos Tapia (b) (4)	14 Oct 2020 16:57:47
	(b) (4)	
User entered '31 Aug 2020' reason for change: Per Query Resolution	Milagritos Tapia (b) (4)	14 Oct 2020 16:57:47
	(b) (4)	
User opened query 'PV Query: Please consider updating start date to date of onset of symptoms.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:26:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
	(b) (4), (b) (6)	
User entered '13 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:03:14
	(b) (4), (b) (6)	

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:33
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 23:58:38
User entered '23:00' reason for change: Per Query Resolution	Milagritos Tapia (b) (4)	15 Oct 2020 23:58:38
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:53
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 16:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 23:00'	System	15 Oct 2020 23:58:38
User entered empty.	System	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:03:14



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'not expected to resolve' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:10:50
DataPoint Verified.	Kaitlin Mason (b) (4)	09 Nov 2020 20:00:08
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:33
	(b) (4), (b) (6)	14 Oct 2020 20:07:14
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:25:32
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	14 Oct 2020 20:06:01
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:10:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:33:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:41
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered '1' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:10:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'Related (RELATED)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:10:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:06:01
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:10:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 19:13:16
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 21:50:43
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	09 Nov 2020 19:59:54
DataPoint Un-verified.	(b) (4)	
	Kaitlin Mason (b) (4)	09 Nov 2020 19:58:05
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Kaitlin Mason (b) (4)	09 Nov 2020 19:58:05
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 14:21:24
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	14 Oct 2020 20:06:01
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Sep 2020 16:03:14
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 19:13:16
DataPoint Un-verified.	Kaitlin Mason (b) (4)	09 Nov 2020 19:58:05
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	09 Nov 2020 19:58:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:20:05
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 14:11:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	(b) (4), (b) (6)	01 Dec 2020 14:11:13
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) (6)	10 Nov 2020 14:10:57
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 'Not expected to resolve' (Site from Safety).	Kaitlin Mason (b) (4)	09 Nov 2020 19:59:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
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)	13 Oct 2020 20:25:47
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:10:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:03:14
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[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 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'PV query: Please provide the subsequent Rheumatology four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' (Site from Safety). Query 'PV query: Please provide the subsequent Rheumatology four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' answered with 'Records have been provided.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:46:55
User opened query 'PV query: Please provide the subsequent Rheumatology four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' (Site from Safety). Query 'PV query: Please provide the subsequent Rheumatolgy four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' canceled (Site from Safety).	Milagritos Tapia (b) (4) (b) (4)	29 Dec 2020 19:25:50
User opened query 'PV query: Please provide the subsequent Rheumatology four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' (Site from Safety). Query 'PV query: Please provide the subsequent Rheumatolgy four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 20:26:25 10 Dec 2020 20:26:12
User closed query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting left hip/outer thigh pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 13:22:55



US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting left hip/outer thigh pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' answered with 'participant reports that left hip/outer thigh pain is not in the hip joint - stated that it is about 8-10 inches below the hip join and was the result of a surgical boot he was required to wear back in January 2020 ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	30 Nov 2020 17:08:18
User opened query 'PV query: Please provide the subsequent Rheumatology four week follow-up office visit notes, cervical spine x-ray results (ordered 20 Oct), and any other documentation relevant to evaluation of the event of rheumatoid arthritis to safety_Moderna@iqvia.com. Please leave query open until records are provided.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 22:19:19
User opened query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting left hip/outer thigh pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 22:19:06
User closed query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting hip pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:23:47
User closed query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:23:45

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting hip pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' answered with 'Called participant to clarify hip pain - stated that it is more of a left outer thigh pain that began with wearing an ill fitting surgical boot. Medical history updated accordingly ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 18:01:20
Query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'Follow up notes sent to email address above' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	20 Nov 2020 17:04:52
User opened query 'PV query: It was reported that patient had no medical history of joint pain/swelling, while also reporting hip pain in January 2020. Please clarify and provide the etiology for the ongoing hip pain which originated in January 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 23:13:22
User opened query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 23:13:12
User closed query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 17:43:14

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2089 of 2743

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'Office visit notes sent via email November 18th at 10:44 to Safety_Moderna@iqvia.com. ' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	18 Nov 2020 15:44:32
User opened query 'PV Query: Rheumatology notes received were from visit on 9/29 with plans to follow-up in 2 weeks. Please provide follow-up Rheumatology office visit notes and any diagnostic exams/laboratory results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 18:35:49
User closed query 'PV Query: Please provide office visit notes and any diagnostic exams/laboratory results from the additional planned follow-up with Rheumatology with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 17:12:23
Query 'PV Query: Please provide office visit notes and any diagnostic exams/laboratory results from the additional planned follow-up with Rheumatology with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' answered with 'PROVIDED' (Site from Safety).	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:36:07
User opened query 'PV Query: Please provide office visit notes and any diagnostic exams/laboratory results from the additional planned follow-up with Rheumatology with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 21:28:11

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify if subject had joint pain or swelling in the (recent) past prior to the vaccine.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:41:26
User closed query 'PV Query: Please provide the dates the rheumatoid factor and anti-CCP AB tests were performed.' (Site from Safety).		15 Oct 2020 12:41:24
User closed query 'PV Query: Please report the treatment received by the subject, including any procedures.' (Site from Safety).		15 Oct 2020 12:41:22
User closed query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).		15 Oct 2020 12:41:21
User closed query 'PV Query: Please provide results of any diagnostic studies done to evaluate the event (lab testing, imaging, biopsies, etc).' (Site from Safety).		15 Oct 2020 12:41:19
User closed query 'PV Query: Please provide rheumatology consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		15 Oct 2020 12:41:15
User closed query 'PV Query: Describe the clinical course of the event, including signs and symptoms.' (Site from Safety).		15 Oct 2020 12:41:13
User closed query 'PV Query: Please indicate any risk factors the subject had for the development of the event, please provide relevant medical history including history of autoimmune disorders (MS, lupus, RA, IBD, psoriasis, etc) with onset date(s), severity, treatment and relevant details.' (Site from Safety).		15 Oct 2020 12:41:10
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
Query 'PV Query: Please provide rheumatology consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'The note has been sent via email.' (Site from Safety).	Milagritos Tapia (b) (4) (b) (4)	14 Oct 2020 17:49:07

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2091 of 2743

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide results of any diagnostic studies done to evaluate the event (lab testing, imaging, biopsies, etc).' answered with 'All results are provided in the consult note that has been sent.' (Site from Safety).	Milagritos Tapia (b) (4)	14 Oct 2020 17:48:26
Query 'PV Query: Please report the treatment received by the subject, including any procedures.' answered with 'The participant took tylenol to treat the pain.' (Site from Safety).	Milagritos Tapia (b) (4)	14 Oct 2020 17:47:48
Query 'PV Query: Please provide the dates the rheumatoid factor and anti-CCP AB tests were performed.' answered with 'These were collected on 25 September 2020.' (Site from Safety).	Milagritos Tapia (b) (4)	14 Oct 2020 17:46:50
Query 'PV Query: Please clarify if subject had joint pain or swelling in the (recent) past prior to the vaccine.' answered with 'Denied join pain/swelling in the past' (Site from Safety).	Kaitlin Mason (b) (4)	14 Oct 2020 14:15:02
Query 'PV Query: Please report if there were any factors that precipitated the event.' answered with 'No precipitating factors outside of vaccination ' (Site from Safety).	Kaitlin Mason (b) (4)	14 Oct 2020 14:14:38
Query 'PV Query: Describe the clinical course of the event, including signs and symptoms.' answered with 'Included in narrative ' (Site from Safety).	Kaitlin Mason (b) (4)	14 Oct 2020 14:14:22
Query 'PV Query: Please indicate any risk factors the subject had for the development of the event, please provide relevant medical history including history of autoimmune disorders (MS, lupus, RA, IBD, psoriasis, etc) with onset date(s), severity, treatment and relevant details.' answered with 'No history of risk factors or precipitating conditions. MH up to date' (Site from Safety).	Kaitlin Mason (b) (4)	14 Oct 2020 14:13:52
User opened query 'PV Query: Please clarify if subject had joint pain or swelling in the (recent) past prior to the vaccine.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:26:27
User opened query 'PV Query: Please provide the dates the rheumatoid factor and anti-CCP AB tests were performed.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:24:29
User opened query 'PV Query: Please report the treatment received by the subject, including any procedures.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:24:19

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2092 of 2743

US3742169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please report if there were any factors that precipitated the event.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:24:07
User opened query 'PV Query: Please provide results of any diagnostic studies done to evaluate the event (lab testing, imaging, biopsies, etc).' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:23:58
User opened query 'PV Query: Describe the clinical course of the event, including signs and symptoms.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:23:48
User opened query 'PV Query: Please provide rheumatology consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:23:38
User opened query 'PV Query: Please indicate any risk factors the subject had for the development of the event, please provide relevant medical history including history of autoimmune disorders (MS, lupus, RA, IBD, psoriasis, etc) with onset date(s), severity, treatment and relevant details.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 20:23:27
DataPoint Un-verified.	(b) (4), (b) (6)	03 Oct 2020 15:10:36
User entered 'After first vaccination, he reported in the e-diary muscle and joint ache/pain through day 7. Muscle and joint ache/pain started again on Sunday the 13th of September, but was doing better by time of the Day 15 phone call on the 16th of September. Later that day, the joint ache and pain started again and continued. It was improved with Tylenol which he stopped taking on the 24th of September. He also experienced some tinnitus, insomnia and constipation post vaccination. On 9/29 he was seen by a rheumatologist who diagnosed him with rheumatoid arthritis. Significant laboratory results returned on 02 October 2020 and include rheumatoid factor 62.5 IU/ml (normal 0-13) and anti-CCP Ab >250 units (normal <20).' reason for change: New Information	(b) (4), (b) (6)	03 Oct 2020 15:10:36

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2093 of 2743

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:03:14

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:10:36



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:10:36

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User coded data point as SOC: Ear and labyrinth disorders, HLG: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:54:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:54:00
Data point term sent to Coder	System	25 Sep 2020 16:04:26
User entered 'TINNITUS'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

US3742169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:06:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 16:06:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Sep 2020 16:06:29
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 16:04:11
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '20 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User entered empty.	System	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '22 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User entered empty.	System	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'l'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Sep 2020 16:04:11



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User entered '0'	System	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17
User entered '0'	System	25 Sep 2020 16:04:11

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:17

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25

US3742169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:54:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:54:05
Data point term sent to Coder	System	25 Sep 2020 16:05:27
User entered 'VOMITING'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '19 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User entered empty.	System	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '20 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User entered empty.	System	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'l'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User entered '0'	System	25 Sep 2020 16:05:07

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25
User entered '0'	System	25 Sep 2020 16:05:07



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:25

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32

US3742169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:54:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 16:54:08
Data point term sent to Coder	System	25 Sep 2020 16:06:27
User entered 'INSOMNIA'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '7 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User entered empty.	System	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User entered empty.	System	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'l'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Sep 2020 16:06:12



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User entered '0'	System	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32
User entered '0'	System	25 Sep 2020 16:06:12

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:32

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:32:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:32:42
Data point term sent to Coder	System	27 Oct 2020 16:31:19
User entered 'CONSTIPATION'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45



US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '22 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User entered empty.	System	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
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)	23 Feb 2021 11:03:06
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 'data updated' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:27:43
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 17:26:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 17:26:08
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)	18 Jan 2021 05:32:22
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 17:26:08
User entered '09 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 17:26:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User entered empty.	System	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45



US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#8 & 11) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 18:29:40
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#8 & 11) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Dec 2020 18:30:13
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	02 Dec 2020 18:30:08
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Dec 2020 18:30:08
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#8 & 11) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:13:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	28 Oct 2020 13:47:29
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	28 Oct 2020 13:47:29
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Oct 2020 16:30:45
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
DataPoint Un-verified.	Kaitlin Mason (b) (4)	02 Dec 2020 18:30:08
User entered '1' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	02 Dec 2020 18:30:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered '0'	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

US3742169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:28:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 17:26:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 17:26:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:47
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 13:47:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 13:47:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 16:30:45
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:47
User entered empty.	Sherry McCammon (b) (4) (b) (4)	27 Oct 2020 16:30:45

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User entered '0'	System	28 Oct 2020 13:47:29

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08
User entered '0'	System	28 Oct 2020 13:47:29



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:54:08

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 15:26:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 15:26:05
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:42:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:42:02
Data point term sent to Coder	System	19 Nov 2020 20:26:29
Coding entries removed.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:26:27
User entered 'VIRAL ILLNESS UNSPECIFIED' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:26:27
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 18:34:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 18:34:01
Data point term sent to Coder	System	19 Nov 2020 18:18:40
User entered 'Viral Syndrome'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '31 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User entered empty.	System	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '14 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User entered empty.	System	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:22:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:22:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 18:18:16
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

US3742169

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:28:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 20:23:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Nov 2020 18:18:16
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Nov 2020 20:23:08
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	19 Nov 2020 18:18:16



**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:20:05
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:18:16

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User entered '0'	System	19 Nov 2020 20:22:52

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38
User entered 'I'	System	19 Nov 2020 20:22:52

**US3742169**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 20:54:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:28:34**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:34:19
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:44:30

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: RABEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:47:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:47:43
Data point term sent to Coder	System	11 Sep 2020 22:47:06
User entered 'RABEPRAZOLE'	Kaitlin Mason (b) (4)	11 Sep 2020 22:47:01
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '20'	Kaitlin Mason (b) (4)	11 Sep 2020 22:47:01
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'once daily (QD)'	Kaitlin Mason (b) (4)	11 Sep 2020 22:47:01
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN UNK 2010'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4)	11 Sep 2020 22:47:01
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:47:01

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:47:01



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 20:36:59
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 20:36:59
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	01 Oct 2020 20:35:30 01 Oct 2020 20:35:28
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:48:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:48:44
Data point term sent to Coder User entered 'LEVOTHYROXINE'	System Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:08 11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'HYPOTHYROIDISM'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '100'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'ug (ug)'	Kaitlin Mason (b) (4)	11 Sep 2020 22:48:04
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN UNK 1990'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4)	11 Sep 2020 22:48:04
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:48:04



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:48:04

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:48:04

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: ENALAPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Oct 2020 20:37:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:37:00
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	01 Oct 2020 20:35:29 01 Oct 2020 20:35:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: ENALAPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:51:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 22:51:52
Data point term sent to Coder User entered 'ENALAPRIL'	System Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:15 11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'HYPERTENSION'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '5'	Kaitlin Mason (b) (4)	11 Sep 2020 22:50:05
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN UNK 2018'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4)	11 Sep 2020 22:50:05
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:50:05

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:50:05

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:48:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:48:01
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 18:46:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:46:39
	(b) (4), (b) (6)	
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 18:46:39
	(b) (4), (b) (6)	
User entered 'BREO Ellipta' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:46:39
	(b) (4), (b) (6)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:37:00
	(b) (4)	
	(b) (4)	
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 20:37:00
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 20:35:29
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
	(b) (4), (b) (6)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:52:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:52:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:51:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:51:54
Data point term sent to Coder User entered 'BREO'	System Kaitlin Mason (b) (4)	11 Sep 2020 22:51:18 11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'ASTHMA'	Kaitlin Mason (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:42:35
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 12:08:25
User entered '100/25' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Oct 2020 12:08:15
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:49:12
User entered '25/' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:49:12
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puffs. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:18:38
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'I'	Kaitlin Mason (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:46:39
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:46:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'puff (PUFF)'	Kaitlin Mason (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kaitlin Mason (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN Aug 2020'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4)	11 Sep 2020 22:51:02
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:51:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:51:02

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 20:36:59
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 20:36:59
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	01 Oct 2020 20:35:30 01 Oct 2020 20:35:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:52:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:52:40
Data point term sent to Coder User entered 'ALBUTEROL'	System Kaitlin Mason (b) (4)	11 Sep 2020 22:52:20 11 Sep 2020 22:52:06



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'ASTHMA'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:42:41
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:35:30
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:34:20
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:34:20
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:23:49
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '1'	Kaitlin Mason (b) (4)	11 Sep 2020 22:52:06
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:34:20
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:34:20
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'puff (PUFF)'	Kaitlin Mason (b) (4)	11 Sep 2020 22:52:06
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4)	11 Sep 2020 22:52:06
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'as needed (PRN)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN UNK 2000'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4)	11 Sep 2020 22:52:06
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:52:06

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:52:06



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:52:06

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 18:39:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:39:43
Data point term sent to Coder	System	29 Oct 2020 18:39:36
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 18:39:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:37:00
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 20:37:00
Data point term sent to Coder	System	01 Oct 2020 20:35:32
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:53:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:53:41
Data point term sent to Coder	System	11 Sep 2020 22:53:21
User entered 'LEVOCETIRIZINE'	Kaitlin Mason (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 14:42:54
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 18:39:25
DataPoint Un-verified.	(b) (4), (b) (6)	29 Oct 2020 18:39:10
User entered 'ENVIRONMENTAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:39:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:18:33
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'SEASONAL ALLERGIES'	Kaitlin Mason (b) (4)	11 Sep 2020 22:53:02
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '5'	Kaitlin Mason (b) (4)	11 Sep 2020 22:53:02
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'mg (mg)'	Kaitlin Mason (b) (4)	11 Sep 2020 22:53:02
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'once daily (QD)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN UNK 2018'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:53:02



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:53:02

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:53:02

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 20:37:00
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 20:37:00
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	01 Oct 2020 20:35:32 01 Oct 2020 20:35:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:56:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 22:56:42
Data point term sent to Coder User entered 'MONTELUKAST'	System Kaitlin Mason (b) (4)	11 Sep 2020 22:55:23 11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'ENVIRONMENTAL ALLERGIES'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '10'	Kaitlin Mason (b) (4)	11 Sep 2020 22:54:25
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'mg (mg)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4)	11 Sep 2020 22:54:25
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'once daily (QD)'	Kaitlin Mason (b) (4)	11 Sep 2020 22:54:25
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4)	11 Sep 2020 22:54:25
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'UN UNK 1990'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	Kaitlin Mason (b) (4)	11 Sep 2020 22:54:25
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:54:25

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:54:25

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Oct 2020 20:37:00
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 20:37:00
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	01 Oct 2020 20:35:30 01 Oct 2020 20:35:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: FIBRE, DIETARY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 16:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 16:53:36
Data point term sent to Coder User entered 'FIBER GUMMIES'	System (b) (4), (b) (6)	25 Sep 2020 15:57:12 25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'CONSTIPATION'	(b) (4), (b) (6)	25 Sep 2020 15:57:11



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '2'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'GUMMIES'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '15 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 15:57:11



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:49:15
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CONTINUES TO TAKE TO PREVENT CONSTIPATION' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:06:31
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:28:45
Data hard unlocked.	(b) (4), (b) (6)	26 Oct 2020 12:28:37
Data hard locked.	(b) (4), (b) (6)	26 Oct 2020 12:28:33
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:57:11

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 14:49:13
	(b) (4), (b) (6)	28 Oct 2020 15:59:30
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'ENTERED IN ERROR' (Site from DM). DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:06:44
	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:06:37
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:06:37
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 12:28:14
	(b) (4), (b) (6)	01 Oct 2020 20:35:28

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 15:57:11

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 15:57:11



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE;THEOBROMA CACAO OIL, PRODUCTSYNONYM: PREPARATION H [PHENYLEPHRINE HYDROCHLORIDE;THEOBROMA CACAO OIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:36:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 18:36:47
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:30
Data point term sent to Coder	System	27 Oct 2020 17:05:31
DataPoint Un-verified.	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
User entered 'PHENYLEPHRINE/ COCOA BUTTER 0.25/88% SUPPOSITORIES' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
Data point term sent to Coder	System	01 Oct 2020 20:35:30
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
Data point term sent to Coder	System	25 Sep 2020 16:00:17
User entered 'PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'CONSTIPATION'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name (PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES 0.25/88%), and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:11:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:30
Query 'Per DM CLR: Please provide the strength of this medication in the medication name (PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES 0.25/88%), and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:05:21
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:05:14
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:05:14
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name (PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES 0.25/88%), and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:30:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0.25/ 88'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:30
DataPoint Un-verified.	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
User entered 'APPLICATION' reason for change:	(b) (4)	
Data Entry Error	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'PERCENT'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:59:51



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Rectal (RECTAL)'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '16 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '16 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 15:59:51

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 07:12:43
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:30
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:05:29
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:05:14
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 17:05:14
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 12:30:22

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 15:59:51



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User entered empty.	System	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User entered empty.	System	25 Sep 2020 15:59:51

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:43
User entered empty.	System	25 Sep 2020 15:59:51

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 05:42:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 05:42:09
Data point term sent to Coder	System	17 Nov 2020 20:06:40
Coding entries removed.	Kaitlin Mason (b) (4)	17 Nov 2020 20:05:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:21:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:21:21
Data point term sent to Coder	System	05 Oct 2020 17:52:44
Coding entries removed.	Kaitlin Mason (b) (4)	05 Oct 2020 17:52:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:37:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:37:00
Data point term sent to Coder	System	01 Oct 2020 20:35:33
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 09:01:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 09:01:43
Data point term sent to Coder	System	25 Sep 2020 16:02:21
User entered 'TYLENOL GEL CAPS'	(b) (4), (b) (6) (b) (4)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User closed query ' Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 17:18:22
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) (6)	04 Dec 2020 17:18:21
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 'within time frame of RA AE' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:08:59
Query ' Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'Updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:06:13
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:05:56
User entered 'rheumatoid arthritis' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:05:56
User opened query ' Per DM CLR: Please provide the specific location of joint pain (eg, generalized arthralgia knee joint pain, shoulder joint pain, etc.) Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:13:24

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2446 of 2743

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

[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. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 07:12:44
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'JOINT PAIN'	(b) (4), (b) (6)	25 Sep 2020 16:01:38



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '650'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'as needed (PRN)'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 16:01:38

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
DataPoint Un-verified.	Kaitlin Mason (b) (4)	05 Oct 2020 17:52:33
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	05 Oct 2020 17:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Other (OTHER)'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Per CDM: Kindly provide the meaning of acronym TIB. Please enter this in "If route of administration is Other, specify" field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 10:21:38
Query 'Per CDM: Kindly provide the meaning of acronym TIB. Please enter this in "If route of administration is Other, specify" field as appropriate. ' answered with 'UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:52:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Oct 2020 17:52:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:52
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User opened query 'Per CDM: Kindly provide the meaning of acronym TIB. Please enter this in "If route of administration is Other, specify" field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 10:19:14
User entered 'T.I.B'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '16 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:01:38



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered '24 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:34

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 16:34:18
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, 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)	17 Nov 2020 20:08:46
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:05:56
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:05:56
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:14:19
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:35:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User entered empty.	System	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User entered empty.	System	25 Sep 2020 16:01:38

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:36
User entered empty.	System	25 Sep 2020 16:01:38

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Nov 2020 03:50:49
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 Nov 2020 03:50:49
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
Data point term sent to Coder	System	13 Oct 2020 17:03:47
Data point term sent to Coder	System	06 Oct 2020 14:07:08
User entered 'TRUNATURE DIGESTIBE PROBIOTIC'	(b) (4), (b) (6)	06 Oct 2020 14:06:20



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'CONSTIPATION'	(b) (4), (b) (6)	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:03:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:03:26
User entered '2' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 17:03:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:06:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:03:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:03:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 17:03:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:06:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'gummies' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 17:03:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:03:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:03:26
User entered 'as needed (PRN)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 17:03:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:06:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:03:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:03:26
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 17:03:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:06:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered '23 Sep 2020'	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered '0'	(b) (4), (b) (6)	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User closed query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 20:53:30
Query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' answered with 'constipation still ongoing' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	17 Nov 2020 20:09:39
User opened query 'Per DM CLR: The corresponding AE has resolved, however the medication is still ongoing. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:11:31
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:07:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 14:07:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 14:07:07
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:06:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 17:03:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 17:03:26
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 17:03:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 14:06:20
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:06:20

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:06:20



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:06:20

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 17:05:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 17:05:16
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 17:04:48
User entered 'TYLENOL'	Sherry McCammon (b) (4)	13 Oct 2020 17:04:31
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'RHEUMATOID ARTHRITIS'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered '1000'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 17:04:31
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'as needed (PRN)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 17:04:31
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 17:04:31
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered '9 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered '0'	Sherry McCammon (b) (4)	13 Oct 2020 17:04:31
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	Sherry McCammon (b) (4)	13 Oct 2020 17:04:31
	(b) (4)	

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:04:31



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:04:31

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:04:31

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:58:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:58:51
Data point term sent to Coder	System	19 Nov 2020 20:30:38
User entered 'FLU VACCINE'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'VIRAL ILLNESS UNSPECIFIED'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '0.5'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'mL (mL)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28



US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'once (ONCE)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'Intramuscular (INTRAMUSCULAR)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '02 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '02 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User entered empty.	System	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User entered empty.	System	19 Nov 2020 20:30:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:23
User entered empty.	System	19 Nov 2020 20:30:28

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:42:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 20:42:05
Data point term sent to Coder	System	19 Nov 2020 20:40:58
User entered 'XYZAL'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:42:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:42:46
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:42:46
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:40:12
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'VIRAL ILLNESS UNSPECIFIED'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '3.75'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'as needed (PRN)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '31 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '0'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '14 Nov 2020'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User entered empty.	System	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User entered empty.	System	19 Nov 2020 20:40:12

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:30
User entered empty.	System	19 Nov 2020 20:40:12

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:34

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 18:17:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:17:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:02:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 18:02:05
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	22 Feb 2021 18:01:06 22 Feb 2021 18:00:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:17:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 02:17:16
Data point term sent to Coder	System	01 Dec 2020 14:04:45



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Mobic'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:00:26
User entered 'Rheumatoid Arthritis' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 18:00:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'Viral Illness unspecified'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '15'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 14:03:55



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 14:03:55

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (31 OCT 2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 20 OCT 2020. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:05:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (31 OCT 2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 20 OCT 2020. ' answered with 'updated corresponding AE' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 18:00:35
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE (31 OCT 2020). Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 20 OCT 2020. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:10:35
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '20 Oct 2020'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered '0'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 14:03:55

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:21:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 14:05:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 14:03:55



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 14:03:55

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 14:03:55

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Jan 2021 14:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Jan 2021 14:27:40
Data point term sent to Coder User entered 'Celebrex'	System Hassan Haji (b) (4) (b) (4)	07 Jan 2021 14:27:17 07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'No (N)'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'rheumatoid arthritis'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '200'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'mg (mg)'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered empty.	Hassan Haji (b) (4)	07 Jan 2021 14:26:28



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'twice daily (BID)'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered empty.	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered empty.	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '7 Dec 2020'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered '0'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'Yes (Y)'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered empty.	Hassan Haji (b) (4)	07 Jan 2021 14:26:28



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 21:11:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
User entered 'No (N)'	Hassan Haji (b) (4)	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Jan 2021 14:26:28

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 14:26:28

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: TRIAMCINOLONE ACETONIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:37:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:37:46
Data point term sent to Coder	System	04 Mar 2021 20:44:47
User entered 'triamcinolone acetone'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'elbow pain R/T rheumatoid arthritis'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered '40'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'mg (mg)'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'once daily (QD)'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'Other (OTHER)'	Sherry McCammon (b) (4)	04 Mar 2021 20:43:47
	(b) (4)	

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:28:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'intraarticular'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered '17 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered '0'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered '17 Dec 2020'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:07:07
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User entered '1'	System	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User entered '1'	System	04 Mar 2021 20:43:47

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:21:52
User entered '804 (804)'	System	04 Mar 2021 20:43:47

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: OTHER IMMUNOSUPPRESSANTS, PRODUCT: HYDROXYCHLOROQUINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:51:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:51:40
Data point term sent to Coder	System	23 Mar 2021 19:51:21
User entered 'Hydroxychloroquine'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:50:27



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered 'Rheumatoid Arthritis'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered '200'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:50:27



**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered '19 Mar 2021'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered '0'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:28:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 17:44:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 17:44:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 17:44:48
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Mar 2021 19:50:27
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:24:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 19:06:20
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 19:50:27

**US3742169**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:28:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 19:50:27



US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:28:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:22:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 21:10:54

**US3742169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:28:34**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered '20 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 21:12:07

**US3742169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered 'MRI of left hip'	(b) (4), (b) (6)	30 Nov 2020 21:12:07

US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:17:39
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:08:14
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:19:59
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 13:19:59
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:19:59
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'MRI was done for left hip to rule out viral illness. MRI ordered by rheumatologist. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 20:08:13
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:23:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:23:17
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	30 Nov 2020 21:13:09
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	30 Nov 2020 21:12:07
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Nov 2020 21:12:07

US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:34

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:17:39
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:19:59
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 13:19:59
User entered 'Viral Illness Unspecified' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:19:59
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 21:13:09
User entered 'Left hip pain R/T Viral illness'	(b) (4), (b) (6)	30 Nov 2020 21:12:07

**US3742169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:28:34**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered '20 Nov 2020'	(b) (4), (b) (6)	30 Nov 2020 21:14:14

**US3742169**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:19
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered 'X-Ray of neck'	(b) (4), (b) (6)	30 Nov 2020 21:14:14

US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:17:39
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:08:33
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:20:28
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 13:20:28
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:20:28
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'XRAY was done for neck to rule out viral illness. XRAY ordered by rheumatologist.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 20:09:52
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:23:39
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	30 Nov 2020 21:14:14



US3742169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:34

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:17:39
User signature succeeded.	Milagritos Tapia (b) (4)	12 Apr 2021 14:48:51
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:20:28
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 13:20:28
User entered 'Viral Illness Unspecified' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:20:28
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 17:23:17
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 21:14:14

**US3742169**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 10 Jun 2021 09:28:34**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:59:46
User entered '3 Oct 2020'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:09:59

US3742169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:28:34

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:11:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:03
User closed query 'Per CDM: there si an SAE that is recorded as IP Withdrawn. Please consider updating this field to SAE (Specify)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:01:21
Query 'Per CDM: there si an SAE that is recorded as IP Withdrawn. Please consider updating this field to SAE (Specify)' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:15:29
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:13:59
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:13:59
User opened query 'Per CDM: there si an SAE that is recorded as IP Withdrawn. Please consider updating this field to SAE (Specify)' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:50:54
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:46
User entered 'AE (specify) (ADVERSE EVENT)'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:09:59

US3742169

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:28:34

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 04:11:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:21:03
User closed query 'Per CDM: since IP was discontinued to as SAE please recorded the SAE record number (i.e. SAE #1 referencing log line # )' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:01:23
Query 'Per CDM: since IP was discontinued to as SAE please recorded the SAE record number (i.e. SAE #1 referencing log line # )' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:16:23
User entered 'SAE (AE#2)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:16:18
User entered 'SAE USA-US127-2020-MRNA-1273-P301000003' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:14:52
User entered 'SAE' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	24 Nov 2020 17:13:59
User opened query 'Per CDM: since IP was discontinued to as SAE please recorded the SAE record number (i.e. SAE #1 referencing log line # )' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:54:00
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:49:34
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	19 Nov 2020 15:27:17
DataPoint Un-verified.	Kaitlin Mason (b) (4) (b) (4)	19 Nov 2020 15:27:12
User entered 'AE 2' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	19 Nov 2020 15:27:12
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:47:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:46
User entered 'RHEUMATOID ARTHRITIS'	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 17:09:59

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered '05/Oct/2020 13:32'	System	05 Oct 2020 13:32:44

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:28:34

**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 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:05
User entered '15/Oct/2020 08:41'	System	15 Oct 2020 12:41:42

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:28:34

**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 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 00:38:46
User entered 'I'		15 Oct 2020 12:41:42



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:00:05
User entered '15/Oct/2020 20:38'	System	16 Oct 2020 00:38:54

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:28:34

**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 17:29:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:11:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:00:05
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 00:38:54

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:34

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:59:47
User entered '10/Nov/2020 14:11'	System	10 Nov 2020 14:11:30

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:28:34

**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 17:29:16
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:31:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 16:59:47
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:11:30

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 19:11:23
User entered '24/Nov/2020 08:31'	System	24 Nov 2020 13:31:42

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:28:34

**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 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:11:23
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 18:00:04
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 13:31:42

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered	System	05 Oct 2020 13:32:04
'USA-US127-2020-MRNA-1273-P301000003'		

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'No (N)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Yes (Y)'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Karen'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Kotloff'	System	05 Oct 2020 13:32:04



**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '685 W. Baltimore Street, HSF 480'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'Baltimore'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:28:06
User entered 'MD'	Milagritos Tapia (b) (4) (b) (4)	24 Dec 2020 03:39:03

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered '21201'	System	05 Oct 2020 13:32:04

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:41:34
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:04:55
User entered 'US'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
	(b) (4)	
User entered '6'	System	01 Dec 2020 18:00:19
User entered '5'	System	24 Nov 2020 13:31:42
User entered '4'	System	10 Nov 2020 14:11:30
User entered '3'	System	16 Oct 2020 00:38:54
User entered '2'	System	15 Oct 2020 12:41:42
User entered '1'	System	05 Oct 2020 13:32:44

**US3742169**

**Folder: SAE USA-US127-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:28:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 19:11:23
User entered '01/Dec/2020 18:00'	System	01 Dec 2020 18:00:19

US3742169

Folder: SAE USA-US127-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:28:34

**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 17:29:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Dec 2020 19:11:23
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 18:00:19