

US3742169 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

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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

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 31 AUG 2020

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

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Folder OID SCRN

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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 (*dd MMM yyyy*) 31 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

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

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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)	_____

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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)	_____

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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)	_____

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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)	

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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)	_____

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Folder: Screening

Form: Physical Examination

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

Generated On: 10 Jun 2021 09:28:34

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

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

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**Occupational Risk**

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**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

---

**Specify** \_\_\_\_\_

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

---

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

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

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

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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

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 31 AUG 2020

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

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Folder OID VISIT1

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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

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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

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 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 ( <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
Temperature ( <i>xxx.x</i> )	097.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	061 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	080 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Generated On: 10 Jun 2021 09:28:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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="checkbox"/> Axillary <input type="checkbox"/> Other <input checked="" type="checkbox"/>
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

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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*) \_\_\_\_\_

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

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Folder: 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

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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

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

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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

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

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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

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Is the participant continuing to the next visit?

Yes

No

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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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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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

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:34

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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.**

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

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.**

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

02 SEP 2020 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.**

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

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.**

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

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.**

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

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.**

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

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.**

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	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

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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

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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

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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

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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

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	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

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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

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:34

Yes

---

PC Time stamp

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PC Open Date & Time

02 SEP 2020 12:00

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PC Close Date & Time

03 SEP 2020 11:59

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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

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:34

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	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

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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

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:34

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	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

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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

US3742169

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:34

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	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

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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

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	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

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US3742169

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 10 Jun 2021 09:28:34

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**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

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**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**

None

**ACHES IN SEVERAL JOINTS**

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 (doctor visit, 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 (doctor visit, 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 (doctor visit, 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   
No

---

Visit date (dd MMM yyyy) 5 OCT 2020

---

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

---

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

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  No

---

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 ( <i>dd MMM yyyy</i> )			5 OCT 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	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   
No

---

Visit date (dd MMM yyyy) 19 NOV 2020

---

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

---

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  No

---

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

Yes

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

No

Yes

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

Date and time of submission 18 NOV 2020 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

Yes

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

No

Yes

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

Date and time of submission 27 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 <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 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 <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 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 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

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 <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 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 <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	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 <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 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 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  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**

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

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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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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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 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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 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 <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	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#) 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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  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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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°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

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   
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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 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 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°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**

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

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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

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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 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  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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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   
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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 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 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 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 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   
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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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   
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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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   
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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 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 348

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 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 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 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°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**

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

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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  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**

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

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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  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**

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

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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

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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 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   
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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#) 26 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 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°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 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 404

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

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

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

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

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

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

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

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

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

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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

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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 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   
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

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  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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<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   
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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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  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**

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

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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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 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 453

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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   
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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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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

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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 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 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 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 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 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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 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°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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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**

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

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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°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 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 516

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 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 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**

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

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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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 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 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   
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**

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

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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**

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

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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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 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 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°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 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 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°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)**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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°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)**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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)**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 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 593

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3742169**

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

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
<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  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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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  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**

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

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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  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)**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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)**

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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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   
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**

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

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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   
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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 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 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°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 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 670

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 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 677

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#) 10 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 684

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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  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)**

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

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

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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  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

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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

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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 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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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   
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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 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 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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 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 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  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**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 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 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   
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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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   
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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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°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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	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  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**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 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 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  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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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°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**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 12 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 16 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 782

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 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 789

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3742169**

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

**Form: Safety Follow Up Diary**

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 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 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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**

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

---

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 NOV 2022 23:59

---

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
<a href="#">No</a>		<a href="#">14 MAR 2021 11:04:45</a>

---

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  No

---

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	Clinic Visit - Scheduled <input type="checkbox"/> Clinical Visit - Unscheduled <input checked="" type="checkbox"/> Safety Call <input type="checkbox"/> Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>

---

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
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

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"/>

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

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

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 (2)

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

Generated On: 10 Jun 2021 09:28:34

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

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)

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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

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

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 (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)

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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

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 (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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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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
- 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 (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"/>

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

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 (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"/>

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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"/>

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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

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

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 (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"/>

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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"/>

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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

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

Mild

Moderate

Severe

Not Done

---

Runny Nose (Rhinorrhea)

None

Mild

Moderate

Severe

Not Done

---

Nausea

None

Mild

Moderate

Severe

Not Done

---

Vomiting

None

Mild

Moderate

Severe

Not Done

---

Diarrhea

None

Mild

Moderate

Severe

Not Done

---

Sore Throat

None

Mild

Moderate

Severe

Not Done

---

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Folder: Covid-19 Assessment 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"/>

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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"/>

---

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EAB) (1725)

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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"/>

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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
- Mild
- Moderate
- Severe
- Not Done

Runny Nose (Rhinorrhea)

- None
- Mild
- Moderate
- Severe
- Not Done

Nausea

- None
- Mild
- Moderate
- Severe
- Not Done

Vomiting

- None
- Mild
- Moderate
- Severe
- Not Done

Diarrhea

- None
- Mild
- Moderate
- Severe
- Not Done

Sore Throat

- None
- Mild
- Moderate
- Severe
- Not Done

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Folder: Covid-19 Assessment 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"/>

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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"/>

---

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EAB) (1725)

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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"/>

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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

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 (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"/>

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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)

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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"/>

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

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 (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"/>

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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"/>

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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

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 (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"/>

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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"/>

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EAB) (1725)

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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

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 (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"/>

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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"/>

---

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EAB) (1725)

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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"/>

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"/>

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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"/>

---

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EAB) (1725)

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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"/>

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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

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 (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"/>

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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)

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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

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

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

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: 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   
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes   
No

Date of Test 06 NOV 2020

Type of Test Performed Nasopharyngeal Swab   
Nasal Swab   
Saliva Test   
Other

Other, specify \_\_\_\_\_

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes   
No

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes   
No

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

---

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   
No

---

Visit date (dd MMM yyyy) 06 NOV 2020

---

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

---

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 ( <i>dd MMM yyyy</i> )	06 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	12:20 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 12:20
Height ( <i>xxx.x</i> )	67.0 in
Weight ( <i>xxx.x</i> )	197.0 lb
Temperature ( <i>xxx.x</i> )	098.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	063 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	084 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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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   
No

---

Visit date (dd MMM yyyy) 9 FEB 2021

---

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

---

Folder OID UNBLND\_DECIDE

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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  No

---

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  No

---

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

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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 <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	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	

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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   
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 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   
No

If not Ongoing, end date (dd MMM yyyy) \_\_\_\_\_

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

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None False

---

Concomitant Medication True

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

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

---

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	

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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: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 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	

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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: _____	
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 (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	

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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: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 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 <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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 JAN 2021
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)

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

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Folder: Adverse Events

Form: Adverse Events (7)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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---

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

Yes

No

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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---

	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"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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

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---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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

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---

	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 ( <i>dd MMM yyyy</i> )	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"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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

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---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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

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---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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

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---

	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 ( <i>dd MMM yyyy</i> )	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"/>

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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

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---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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

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---

	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 ( <i>dd MMM yyyy</i> )	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="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>

---

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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

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---

	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   
No

If not Ongoing, End date (dd MMM yyyy) 16 SEP 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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

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	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   
No

If not Ongoing, End date (*dd MMM yyyy*) 24 SEP 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

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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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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

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---

	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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

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)

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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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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)

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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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 02 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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)

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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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 14 NOV 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

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)

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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   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

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)

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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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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  
EAB) (1725)

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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  
EAB) (1725)

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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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

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)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Due to SARS-COV-2

Other

---

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-P30 1000003
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
<b>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.</b>	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
<b>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.</b>	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
<b>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.</b>	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-P30 1000003
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
<b>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.</b>	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
<b>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.</b>	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
<b>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.</b>	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 '1'	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, HLG: 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: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:56:35
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: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:56:48
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, HLT: 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: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:56:58
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: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 22:57:16
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, HLG: 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, HLG: 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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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 '1'	(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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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 '1'	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'	System	04 Sep 2020 15:15:06
User entered '98.3'	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'	System	02 Sep 2020 04:00:52
User entered '3'	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'	System	05 Sep 2020 03:15:08
User entered '3'	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: 'bcda0a3e-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: 'bcda0a3e-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: 'bcda0a3e-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: 'bcda0a3e-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: 'bcda0a3e-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 '1'	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) (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

[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) (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

[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 '1'	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 '1'	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 '1'	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 '1'	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 '1'	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'	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

[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'	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

[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'	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

[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'	System	24 Dec 2020 13:50:32
User entered '24 Dec 2020 08:50:28'	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

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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'	System	14 Feb 2021 14:50:51
User entered '14 Feb 2021 09:50:47'	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
	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-6efaae1d32fc'	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-6efaae1d32fc'	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-6efaae1d32fc' 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'	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**

[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'	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

[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'	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**

[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'	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**

[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'	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

[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'	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

[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'	System	23 Apr 2021 16:14:07
User entered '23 Apr 2021 12:13:02'	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

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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

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**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

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**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

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**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

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**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)	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) (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)'	(b) (4) Sherry McCammon (b) (4)	(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) (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) (b) (4)	23 Feb 2021 17:29:16
User entered '4 Feb 2021'	Sherry McCammon (b) (4) (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)'	(b) (4) Sherry McCammon (b) (4)	(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.	(b) (4) 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)	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 '1'	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) (4), (b) (6)	30 Mar 2021 18:54:33
User entered 'Yes (Y)'	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

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) (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

[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) (b) (4)	04 Mar 2021 20:39:05

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

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](#)

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Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 20:19:58

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:20:05

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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

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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

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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

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '01 Apr 2021 09:17'	System	01 Apr 2021 20:20:32

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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](#)

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Audit	User	Time (GMT)
User entered '1'	System	10 Apr 2021 13:36:39

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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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: COVID-19 Contact

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[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

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Form: COVID-19 Contact

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[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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

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[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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (1)

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[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

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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

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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

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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

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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) (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

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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) (6)	10 Nov 2020 17:37:26
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 17:25:05

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:48:39

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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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (2)

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[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

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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) (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) (b) (4)	19 Nov 2020 19:48:39

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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

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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) (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) (b) (4)	19 Nov 2020 19:48:39

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:09

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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

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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

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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) (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) (b) (4)	19 Nov 2020 19:49:09

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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) (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) (b) (4)	19 Nov 2020 19:49:09

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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

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

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

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

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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

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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

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

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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

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

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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

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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

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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

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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

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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

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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

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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

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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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:49:33

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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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (4)

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[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

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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) (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) (b) (4)	19 Nov 2020 19:49:33

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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

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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) (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) (b) (4)	19 Nov 2020 19:49:33

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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

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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

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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

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

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

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

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

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

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

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

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

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

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

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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

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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

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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

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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

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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

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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

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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) (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) (b) (4)	19 Nov 2020 19:49:44

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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

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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) (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) (b) (4)	19 Nov 2020 19:49:44

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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

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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

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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

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

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

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

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

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

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

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

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

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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

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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

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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

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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

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

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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

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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) (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) (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) (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) (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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:06

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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

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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

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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) (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) (b) (4)	19 Nov 2020 19:50:06

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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) (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) (b) (4)	19 Nov 2020 19:50:06

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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

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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

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

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

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

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

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

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

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

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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

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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

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

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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

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

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

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

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)'	(b) (4) 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

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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

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

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

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

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

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

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

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

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

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

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

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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

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

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

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

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

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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

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

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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:50:37

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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

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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

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

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

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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

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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

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

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

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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

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

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

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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

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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

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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

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

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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

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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

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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

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

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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)	

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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

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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

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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

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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

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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

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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

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

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

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

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

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

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

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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

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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

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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

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

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

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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

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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

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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

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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

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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

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Folder: Covid-19 Assessment 06 Nov 2020

Form: Symptom Log (11)

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[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

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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

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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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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)'	(b) (4) 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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

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) (b) (4)	23 Feb 2021 17:29:16
User entered 'Day 13 (Day 13)' reason for change:	Sherry McCammon (b) (4)	19 Nov 2020 19:52:17
Data Entry Error	(b) (4)	
User entered empty.	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

[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

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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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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

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

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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:17

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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

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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

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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

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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

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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

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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

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

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

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

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

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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

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

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

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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

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

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

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

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

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

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

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)'	(b) (4) Sherry McCammon (b) (4)	19 Nov 2020 19:52:37

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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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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)	20 Nov 2020 14:44:52
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (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

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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

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).	System	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
User entered '09 Feb 2021' reason for change: Data Entry Error	(b) (4) Kaitlin Mason (b) (4)	08 Apr 2021 19:17:49
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 '6 Jan 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

[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

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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). User signature succeeded.	(b) (4), (b) (6) Milagritos Tapia (b) (4)	14 Apr 2021 14:08:56 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). DataPoint Un-verified.	Kaitlin Mason (b) (4) Kaitlin Mason (b) (4)	08 Apr 2021 19:18:07 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). DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 12:35:44 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) (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 '1'	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.	(b) (4) 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.	(b) (4) 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.	(b) (4) 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.	(b) (4) 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)'	(b) (4) Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31
	(b) (4)	

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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'	(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

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'	(b) (4) Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:47:31

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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.	(b) (4) 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'	(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

[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'	(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

[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

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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

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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

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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.	(b) (4) 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.	(b) (4) 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)'	(b) (4) Kaitlin Mason (b) (4)	10 Apr 2021 13:47:31
	(b) (4)	

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'	(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

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.	(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 \(xxx\)](#)

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)	10 Apr 2021 13:47:31
	(b) (4)	

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)'	(b) (4) Kaitlin Mason (b) (4) (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'	(b) (4) Kaitlin Mason (b) (4) (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) (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).	System	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) (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).	System	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

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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) (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).		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

US3742169

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) (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).	Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:49:46
User entered '01 Apr 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	10 Apr 2021 13:49:36
User entered '09 Feb 2021'	(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	(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)'	(b) (4) Kaitlin Mason (b) (4)	10 Apr 2021 13:42:33
	(b) (4)	

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 '1'	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](#)

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Audit	User	Time (GMT)
User entered '1'	System	10 Apr 2021 13:43:33

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**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 '1'	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](#)

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Audit	User	Time (GMT)
User entered 'OLD29'	System	10 Apr 2021 13:43:51

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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
DataPoint Verified.	(b) (4)	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

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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, HLG: 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

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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

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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)	14 Oct 2020 20:06:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	System	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

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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)	01 Oct 2020 20:32:20
	(b) (4), (b) (6)	
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

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Folder: Adverse Events

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[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) (b) (4)	28 Sep 2020 14:46:52
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

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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
User closed query 'PV Query: Please consider updating start date to date of onset of symptoms.' (Site from Safety).	(b) (4)	15 Oct 2020 12:40:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 20:06:01
Query 'PV Query: Please consider updating start date to date of onset of symptoms.' answered with 'This the earliest day joint pains appeared in diary.' (Site from Safety).	Milagritos Tapia (b) (4)	14 Oct 2020 16:58:58
DataPoint Un-verified.	(b) (4)	14 Oct 2020 16:57:47
User entered '31 Aug 2020' reason for change: Per Query Resolution	Milagritos Tapia (b) (4)	14 Oct 2020 16:57:47
User opened query 'PV Query: Please consider updating start date to date of onset of symptoms.' (Site from Safety).	(b) (4)	13 Oct 2020 20:26:01
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered '13 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

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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
DataPoint Verified.	(b) (4)	28 Oct 2020 15:58:33
	(b) (4), (b) (6)	
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

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**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

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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
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:32:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 16:03:14

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 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)	10 Nov 2020 14:10:50
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).	Kaitlin Mason (b) (4)	09 Nov 2020 20:00:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:58:33
DataPoint Un-verified.	(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

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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
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

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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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:10:36
DataPoint Un-verified.	System	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

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Folder: Adverse Events

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[Death](#)

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

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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

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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

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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

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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
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

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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

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in 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

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[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

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Folder: Adverse Events

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[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

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[Other medically important event](#)

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
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

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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)	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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	

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[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)	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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	

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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)	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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	
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
	(b) (4), (b) (6)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	17 Nov 2020 19:13:16
	(b) (4), (b) (6)	
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)	09 Nov 2020 19:58:05
	Kaitlin Mason (b) (4)	
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), (b) (6)	02 Nov 2020 14:21:24
DataPoint Verified.	(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

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[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) (b) (4)	09 Nov 2020 19:58:05
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	09 Nov 2020 19:58:05
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

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[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

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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)	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
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

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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
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

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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.' 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 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.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 20:26:25
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

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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 joint 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

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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

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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

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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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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).	(b) (4), (b) (6)	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

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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) (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) (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) (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) (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) (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) (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) (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

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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

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Folder: Adverse Events

Form: Adverse Events (2)

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[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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:10:36

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:34

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 15:10:36

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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

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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 '1'	(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

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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

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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

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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 '1'	(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 '1'	(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

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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

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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

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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

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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

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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

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Folder: Adverse Events

Form: Adverse Events (6)

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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) (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) (b) (4)	27 Oct 2020 16:30:45

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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

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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

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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

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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)	28 Oct 2020 13:47:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	27 Oct 2020 16:30:45
	Sherry McCammon (b) (4)	27 Oct 2020 16:30:45
	(b) (4)	

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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

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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

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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

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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

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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

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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

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Folder: Adverse Events

Form: Adverse Events (6)

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[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

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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

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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

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Folder: Adverse Events

Form: Adverse Events (6)

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[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

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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

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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

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Folder: Adverse Events

Form: Adverse Events (6)

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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

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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

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Folder: Adverse Events

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[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)	27 Oct 2020 16:30:45
	(b) (4)	

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[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

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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) (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) (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

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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

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Folder: Adverse Events

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[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

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Folder: Adverse Events

Form: Adverse Events (6)

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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)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	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)	19 Nov 2020 20:22:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	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

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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

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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

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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

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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

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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

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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

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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 '1'	System	19 Nov 2020 20:22:52

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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) (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) (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) (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

[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) (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 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) (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 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) (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

[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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:47:01

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:47:01

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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)	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)	11 Sep 2020 22:48:44
Data point term sent to Coder User entered 'LEVOTHYROXINE'	System Kaitlin Mason (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) (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 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) (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

[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

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:48:04

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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) (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 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) (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

[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

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:50:05

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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)	23 Dec 2020 17:21:54
	(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)	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)	
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) (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

[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 '1'	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

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	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) (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

[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) (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 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) (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

[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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:51:02

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:51:02

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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) (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) (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) (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) (b) (4)	11 Sep 2020 22:52:40
Data point term sent to Coder User entered 'ALBUTEROL'	System Kaitlin Mason (b) (4) (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)	23 Dec 2020 17:21:54
	(b) (4), (b) (6)	
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)	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) (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

[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) (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

[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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:52:06

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:52:06

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 22:52:06

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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
	(b) (4)	
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)	29 Oct 2020 18:39:43
	(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 18:39:43
	(b) (4)	
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
	(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 20:35:32
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
	(b) (4)	
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
	(b) (4)	
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
	(b) (4)	

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) (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

[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) (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

[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 22:53:02

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:34

If 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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:53:02

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:53:02

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:53:02

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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) (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 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) (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

[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 22:54:25

US3742169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:34

If 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 22:54:25

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) (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

[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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:54:25

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 22:54:25

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 22:54:25

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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
	(b) (4)	
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)	01 Oct 2020 20:37:00
	(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 DataPoint Verified.	System	01 Oct 2020 20:35:30
	(b) (4), (b) (6)	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
	(b) (4)	
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
	(b) (4)	
Data point term sent to Coder	System	25 Sep 2020 15:57:12
User entered 'FIBER 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

[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). 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).	(b) (4) (b) (4), (b) (6) Kaitlin Mason (b) (4) (b) (4)	16 Nov 2020 14:49:15 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
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)	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
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 15:57:11

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Sep 2020 15:57:11

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Sep 2020 15:57:11

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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. DataPoint Verified.	Coder Import (b) (4)	13 Nov 2020 18:36:47
Data point term sent to Coder DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 15:59:30
User entered 'PHENYLEPHRINE/ COCOA BUTTER 0.25/88% SUPPOSITORIES' reason for change: Data Entry Error	System	27 Oct 2020 17:05:31
Data point term sent to Coder DataPoint Verified.	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
Data point term sent to Coder DataPoint Verified.	(b) (4)	27 Oct 2020 17:05:14
Data point term sent to Coder User entered 'PHENYLEPHRINE/ COCOA BUTTER SUPPOSITORIES'	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
	(b) (4)	
	System	01 Oct 2020 20:35:30
	(b) (4), (b) (6)	01 Oct 2020 20:35:28
	System	25 Sep 2020 16:00:17
	(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)	27 Oct 2020 17:05:14
Data Entry Error	Kaitlin Mason (b) (4)	27 Oct 2020 17:05:14
DataPoint Verified.	(b) (4)	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 Coding entries removed.	System Kaitlin Mason (b) (4)	17 Nov 2020 20:06:40 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 Coding entries removed.	System Kaitlin Mason (b) (4)	05 Oct 2020 17:52:44 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 DataPoint Verified.	System (b) (4), (b) (6)	01 Oct 2020 20:35:33 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)	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

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) (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
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) 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)	14 Oct 2020 20:09:02
	(b) (4), (b) (6)	
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
DataPoint Verified.	(b) (4) (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
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) (b) (4)	13 Oct 2020 17:03:26
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
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

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:29:16
DataPoint Verified.	(b) (4)	14 Oct 2020 20:09:02
	(b) (4), (b) (6)	
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
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

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
DataPoint Verified.	(b) (4) (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)	14 Oct 2020 20:09:02
	(b) (4), (b) (6)	
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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:06:20

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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

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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

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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) (b) (4)	13 Oct 2020 17:05:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:05:16
Data point term sent to Coder	System	13 Oct 2020 17:04:48
User entered 'TYLENOL'	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

[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
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	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

[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
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	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

[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
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	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 (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
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered '0'	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

[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
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 20:09:02
User entered empty.	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

[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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:04:31

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**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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 17:04:31

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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

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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)	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)	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). User signature succeeded.	(b) (4), (b) (6)	26 Feb 2021 15:05:39
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).	Karen Kotloff (b) (4) (b) (4) (b) (4), (b) (6)	23 Feb 2021 17:29:16 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). DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 08:10:35
User entered '20 Oct 2020'	(b) (4), (b) (6)	23 Dec 2020 17:21:54
	(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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 14:03:55

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 14:03:55

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 14:03:55

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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.	Coder Import (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)	07 Jan 2021 14:27:40
Data point term sent to Coder	System	07 Jan 2021 14:27:17
User entered 'Celebrex'	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

[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)'	(b) (4) 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.	(b) (4) 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)'	(b) (4) Hassan Haji (b) (4) (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.	(b) (4) Hassan Haji (b) (4) (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'	(b) (4) 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)'	(b) (4) Hassan Haji (b) (4) (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.	(b) (4) 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)'	(b) (4) 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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	07 Jan 2021 14:26:28

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Jan 2021 14:26:28

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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) (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 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) (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) (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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	23 Mar 2021 19:50:27

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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

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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 \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 19:50:27

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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) (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) (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) (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) (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
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		
'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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

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		
'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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 (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 '1'	(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		
'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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 (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 '1'		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
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		
'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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 (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 '1'	(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
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		
'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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 (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 '1'	(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
DataPoint Verified.	(b) (4)	14 Oct 2020 20:04:55
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:32:36
User entered 'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
DataPoint Verified.	(b) (4)	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
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 '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
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 '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
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 '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
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 '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
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 '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 '1'	(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
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		
'USA-US127-2020-MRNA-1273-P301000003'	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

Serious

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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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
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 '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 (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 '1'	(b) (4), (b) (6)	01 Dec 2020 18:00:19